

**EVALUATION OF A MINDFULNESS-BASED THERAPEUTIC
APPROACH FOR PEOPLE LIVING WITH DIABETES**

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OVERVIEW OF VOLUME 1

The thesis comprises a literature review of the existing research on interventions to improve self-management of diabetes. An empirical paper describing the conception, designing and evaluation of a new psychological intervention for people with diabetes and self-management problems. The intervention is a mindfulness-based approach formulated for this population. The intervention was piloted with a group and individuals. The evaluation uses both qualitative and quantitative methodology to assess the acceptability, safety and feasibility of the new intervention. The third section of the thesis is a critical appraisal of the process of conducting the empirical research.

CONTENTS

OVERVIEW OF VOLUME 1.....	2
CONTENTS.....	3
TABLE OF FIGURES.....	5
ACKNOWLEDGEMENTS.....	6
DIFFICULTIES IN THE SELF-MANAGEMENT OF DIABETES	7
Abstract.....	8
Introduction.....	9
The management of Diabetes.....	10
Aim of Literature Review	13
Method of Literature Review	14
The Affect of psychological Distress on Self-Management in Diabetes	17
Evaluation of Systematic Reviews.....	21
Extension of Existing Systematic Reviews.....	29
Conclusions.....	36
Discussion.....	37
Have the Questions Been Answered?	37
Future Directions in Interventions in Diabetes Care.....	39
Conclusions.....	44
References	45
EVALUATION OF A MINDFULNESS-BASED THERAPEUTIC APPROACH FOR PEOPLE LIVING WITH DIABETES	50
Abstract.....	51
Introduction	52
Diabetes.....	52
Self-Management of Diabetes.....	52
The Impact of Psychological Factors on Self-management in Diabetes.....	54
Previous Attempts to Enhance Self-Management in Diabetes	55
Our Understanding of Self-Management Problems in Diabetes.....	58
Mindfulness-Based Approaches.....	60
Our Understanding How Mindfulness Might Help with Self-Management Problems in Diabetes.....	62
Evaluating New Interventions.....	64
Mixed Methodology.....	66
Quantitative Study.....	67
Qualitative Study.....	70
Summary of Research Aims	72
Method	74
Design	74
The Setting	74
The Facilitators.....	78
Procedure.....	82
Case Series Analysis	86
Qualitative methods	87

Semi-structured interview	88
Analysis of Qualitative Data	89
Ethical Approval	92
Quantitative Results	93
Qualitative Data	105
1) Was the Intervention Beneficial?	105
2) What Were the Benefits of the Intervention?.....	106
3) How Did the Benefits Come About?	109
4) Negatives of the Intervention?	124
Discussion of Qualitative Results	129
Conclusions	137
Answering the Research Questions.....	137
Methodological Issues.....	139
Designing the Next Phase of the Study.....	141
References	143
 CRITICAL APPRAISAL	149
Introduction.....	150
P1 Expansion of Discussion.....	150
P2 Personal Reflection on the Research Process	157
 REFERENCES	160
 APPENDICES	161

TABLE OF FIGURES

Table 1 Specific Self-management tasks in diabetes (adapted from Schreurs Colland, Kuijer, de Ridder & van Elderen, 2003)	11
Table 2 Demographic and Medical Information for Intervention Completers	80
Table 3: Demographic and Medical Information for Intervention Non-Completers ..	81
Table 4 Showing pre & post anxiety, depression (HADS) and diabetes distress scores (PAID).....	93
Table 5 Weekly Well-Being Scores	95
Table 6 Diabetes self-care scale (mean numbers of days per week recommended behaviours are being performed)	97
Table 7 Mindfulness Awareness and Attention Scale (MAAS)	98
Table 8 Self-Compassion Scale Total Scores	99
Table 9 Showing the items endorsed on the HAT as Helpful or hindering	101
Table 10 Listing the benefits of the mindfulness for diabetes intervention.....	108

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Part 1 (Literature Review)

DIFFICULTIES IN THE SELF-MANAGEMENT OF DIABETES

Abstract

Aim: To describe the evidence of obstacles to effective self-management for people living with diabetes (PLWD). Secondly, to evaluate the effectiveness of interventions designed to improve self-management and/or decrease psychological distress in people living with diabetes. Supplementary questions were to identify which components of the interventions were effective and to describe how the interventions enhanced self-management for PLWD.

Method: Three main reviews (collectively reviewing the literature from 1980 to January 2003) were identified as addressing the question. EMBASE, MEDLINE and PsychINFO were then searched for articles reporting on randomised controlled trials from 2001 onwards concerning persons over 18 years of age with Type 1 or 2 diabetes. The articles retrieved were hand sorted for those measuring behavioural (including HbA_{1c} levels) and psychological outcomes, 8 articles were identified.

Results:

Mental health problems are associated with poorer self-management and higher rates of diabetic complications. The use of didactic information giving interventions over self-management or psychological interventions was not supported. Cognitive behavioural therapy (CBT), Motivational Interviewing (MI), a self-management approach, and a behaviour change theory based approach have shown promise in enhancing diabetes self-management and psychological well-being.

Conclusions:

This paper has shown that whilst there is some evidence that psychological distress negatively affects self-management of diabetes how and why this is, is not well understood. It appears that by and large interventions to help PLWD improve their self-management have taken “off the peg” interventions from other conditions and applied them to diabetes. It has been proposed that a more targeted approach, beginning with researching and understanding why PLWD might struggle to perform self-care behaviours, is more likely to yield an effective and theory driven intervention.

Introduction

Diabetes is a chronic and progressive health condition affecting an increasing number of people of all ages. Diabetes occurs when blood glucose levels become too high because the body cannot process glucose properly. This may be because not enough insulin (a hormone involved in glucose regulation) is produced. This occurs in Type 1 diabetes, which is an autoimmune disease usually diagnosed in childhood or adolescence. It could also be because the body has become insulin resistant, as in Type 2 diabetes which often has a slow onset in adulthood; over three quarters of people with diabetes have this form of it (Diabetes UK, 2003¹).

In the UK, around 1.3 million people have been diagnosed as having diabetes (DOH, 2002). In addition, one million more people are estimated to have undiagnosed diabetes (Diabetes UK, 2003¹). Estimates suggest that the number of people with diabetes worldwide will more than double by 2025 (King, Aubert & Herman, 1998). In the UK Type 2, Diabetes is not distributed equally amongst the population. People who have a family history of diabetes, those who are not physically active or who are overweight or obese are at increased risk of developing diabetes (DOH, 2002). Less well off people and members of ethnic minority groups are more likely to develop diabetes. For example, Type 2 diabetes is six times more common in people of South Asian descent (DOH, 2002). The prevalence of diabetes increases with age such that in the UK one in twenty people over the age of 65 has diabetes (DOH, 2002).

The management of Diabetes

The main treatment aim for people with diabetes is to normalise blood glucose levels because it has been shown that the onset of diabetic complications can be delayed and their progress slowed by optimising blood glucose levels (Diabetes Control and Complications Trial (DCCT) Research Group, 1993; UK Prospective Diabetes Study (UKPDS) Group, 1998¹, 1998²). In Type 2 diabetes an additional management goal is to control blood pressure (UKPDS, 1998³). Diabetic health complications include blindness, kidney failure, heart disease and stroke (Diabetes UK, 2003²).

The process of blood glucose adjustment must be carried out throughout each day based on what is consumed and the person's activity levels. People with diabetes therefore have the task of managing their own blood glucose levels and this is usually referred to as "self-management" or "self-care". The self-management tasks are aimed at maintaining blood glucose levels in a range that avoids hyperglycaemia (high blood sugar), prevents dangerously low blood sugar (hypoglycaemia) and lessens the chance of progressing to macro and microvascular complications. A disease imposes a high burden on sufferers' lives when its course depends upon self-management behaviours (Schreurs et al 2003). It has been suggested by one author that 95% of diabetes management is carried out by patients themselves (Anderson, 1985). Table 1 describes the typical self-management tasks for people with diabetes, which are both onerous and intrusive.

Table 1 Specific Self-management tasks in diabetes (adapted from Schreurs Colland, Kuijer, de Ridder & van Elderen, 2003)

Task	Sign
Self-monitoring	Blood glucose level
Recognising early symptoms and acting upon them	Hypoglycaemia, hyperglycaemia
Medication	Insulin
Self-regulated adaptations in medication	Adaptation of insulin to blood glucose levels, food intake and activity level
Diet	Eating regularly, controlling body weight
Life style recommendations	Regular physical exercise, moderate alcohol, stop smoking
Disease specific tasks	Regular foot and eye checks

The UK government's National Service Framework (NSF) for Diabetes (Department of Health (DOH), 2002) states, "self-management is the cornerstone of effective diabetes care". The main UK charity for people living with diabetes (PLWD) Diabetes UK (2006), echoes this message in the information it provides which emphasises the individual's "responsibilities" in their own diabetes care. However, PLWD have to grasp the complex health message that the occurrence of diabetic complications are partly but not completely within their control (Parry, Peel, Douglas, Lawton, 2006).

Glycosylated haemoglobin (HbA_{1c}) level is often taken as a measure of adequate self-management as it gives an indication of glycaemic control over the previous

three months. However, there are issues about the reliability of inferring level of glycaemic control and efficacy self-management purely from HbA_{1c}. For instance genetic factors play a role in determining HbA_{1c} levels. A diabetic twin study showed that at any glycaemic level there can be high glycaters (who have higher HbA_{1c} levels and enhanced risk of developing complications) and slow glycaters (Sneider et al, 2001).

Many people cope with the demands of managing their diabetes extremely well. However, a significant number of PLWD do not achieve good control of their blood sugar levels and are therefore at increased risk of developing diabetic complications. Poor diabetic control can be the result of physiological factors such as insulin resistance or as a result of stress elevating blood glucose levels (Fosbury, Bosley, Ryle, Sonksen, Judd, 1997). However, the most common reason for poor diabetic control has been shown to be poor self-management of diabetes (Fosbury et al, 1997).

PLWD's level of performance of the self-management tasks recommended by their healthcare teams tends to be low (Steed et al, 2005). The Diabetes Attitudes Wishes and Needs (DAWN) Study (Peyrot et al, 2005) used self-report questionnaires with 5104 randomly selected PLWD and 3827 healthcare providers in 13 countries worldwide to investigate how successful PLWD were at managing their diabetes. Their results showed that only 46% of people with Type 1 diabetes and 39% of people with Type 2 achieved complete success in a minimum of two-thirds of their self-management domains.

The reasons for poor self-care in diabetes are complicated and as this paper will argue not well understood. Despite this many researchers and clinicians have attempted to use a variety of different approaches to try to improve self-management of diabetes.

Aim of Literature Review

- 1) This paper will explore what is known about the obstacles to self-management of diabetes.
- 2) It will review and evaluate the literature to identify which self-management enhancing and/or psychological distress reducing interventions are effective in diabetes.

Michie & Abraham (2004) propose three key questions when evaluating interventions to change health behaviours: i) does it work? (see aim 2) and additionally ii) Which behaviour change techniques work? and iii) How do they work? Therefore, important but supplementary questions are:

- 3) which behaviour change techniques work to enhance the self-management of diabetes
- 4) how do the behaviour change techniques work to enhance the self-management of diabetes

Michie & Abraham (2004) suggest that interventions explicitly using techniques derived from empirically-supported theory use that theory as an explanation of how the intervention works to change behaviour. An initial reading of articles describing interventions to improve self-management in diabetes revealed that many do not

specify the theories upon which they are based. This suggests that answering the supplementary questions may be difficult however it would be very helpful from the point of view of making suggestions for clinicians and researchers seeking to design new interventions in this field.

Method of Literature Review

Medline and PsychINFO were searched for English language systematic reviews of interventions to improve self-management and/or decrease psychological distress in people with diabetes. Three main reviews were identified which will be evaluated in light of the research questions:

- 1) Norris, Engelgau & Narayan (2001) covering self-management interventions in adults with Type 2 diabetes from 1980 to 1999.
- 2) Steed, Cooke & Newman (2003) covering psychosocial outcomes of education, self-management and psychological interventions in Type 1 and 2 diabetes from 1980 to 2001.
- 3) Ismail, Winkley & Rabe-Hesketh (2004) reviewing and conducting a meta-analysis of psychological interventions to improve glycaemic control in adults with Type 2 diabetes covering published and unpublished material from 1983 to January 2003.

An updated a literature review of self-management and psychological interventions for adults with Type 1 or 2 diabetes published from 2001 (since the previous reviews leave a gap for interventions for people with Type 1 diabetes from 2001 and Type 2 from 2003 onwards) will be added. EMBASE, MEDLINE and PsychINFO were searched for published English language articles from 2001 onwards concerning self-

management or psychological interventions for persons over 18 years of age with Type 1 or 2 diabetes. The search terms included Diabetes (and all its subheadings e.g. Diabetic, Type 1, Type 2, Diabetes Mellitus); Self-management; Psychological (and all related subheadings) and Psychiatric (and all related subheadings). As this paper is particularly concerned with interventions showing evidence of behaviour and/or psychological distress change, the articles were then hand sorted for those which were RCTs measuring behavioural (including the proxy measure of HbA_{1c} levels) and emotional outcomes.

Only randomised controlled trials (RCTs) were selected because behaviour and distress change can only be said to be the direct result of an intervention when random and naturally occurring change are controlled for, pre and post designs therefore do not show strong evidence of change (Michie & Abraham, 2004). These studies will be reviewed for information answering the primary research question: which interventions are effective at improving self-management and/or decreasing psychological distress in diabetes? An important part of answering this question is to evaluate the methodological rigor of the RCTs being reviewed. Oakley et al (1995) derived six important criteria of methodological soundness for RCT's (which are based on the principles of the Cochrane Collaboration, 1994):

- 1) using a randomly allocated or matched control group,
- 2) providing pre and post intervention outcome data,
- 3) reporting intention to treat analyses or controlling for differential attrition rates in control and intervention groups,
- 4) reporting all the outcomes relevant to the study's aims,
- 5) describing the intervention in enough detail to allow replication,

6) ensuring that the study had adequate statistical power.

These will be used in deciding how methodologically sound the RCTs are. The subsidiary questions: which behaviour change interventions work and how do they work will be addressed by considering point 5) whether or not the studies provided a clear enough description of the intervention and its theoretical underpinnings to allow for replication of the study. The generalisability of trials will also be considered e.g. whether the sample used is representative of the population for whom the intervention is designed.

The results were tabulated to provide comparison data on: the outcome measures; setting, patient characteristics and recruitment; power calculation and numbers of participants in each arm of the intervention; rate of attrition, intention to treat analysis or controlling for drop out; adequate randomisation procedures; blinding of clinicians, researchers, assessors and participants; adequate descriptions of intervention and comparison conditions to allow replication; length of follow-up; main findings.

Results

The Affect of psychological Distress on Self-Management in Diabetes

Not all people with diabetes experience difficulty managing their condition or develop psychological distress. Rubin & Peyrot (2001) point out that people with diabetes also report positive aspects of living with diabetes such as confidence in themselves, humour and a deeper capacity for self-awareness. However, 41% of the PLWD surveyed by the DAWN study were experiencing poor psychological well-being. Furthermore, Peyrot et al (2005) also found that between 66-74% of the healthcare providers believed that psychological problems adversely affected their patients' adherence to their self-care regimen. In addition, a case study of poorly controlled people with Type I diabetes found that despite the majority of participants not having diagnosable psychiatric illness, they did have a range of emotional difficulties that adversely affected their ability or willingness to self-care (Milton, 1989). This suggests that psychological distress affects many PLWD and this is a potential factor in their difficulties in carrying out self-management tasks.

Rubin & Peyrot (2001) hypothesise that PLWD may experience subclinical levels of emotional distress for a number of reasons: the daily demands of diabetes self-management, living with the reality or fear of diabetes complications and as a possible consequence of the physical fluctuations in blood glucose level. Individuals with diabetes often report diabetes related worries and this was the case in a qualitative study of influences upon self-management in African-American women with Type 2 diabetes, emotional tiredness, "worry" and fear of diabetes complications emerged as common themes (Samuel-Hodge et al, 2000).

A systematic review of the prevalence of clinically diagnosable anxiety in people with diabetes pooled the data for 2584 PLWD and 1492 controls (Grigsby, Anderson, Freedland, Clouse & Lustman, 2002). Grigsby et al (2002) found that Generalised Anxiety Disorder (GAD) was the most common category present in 14% of the PLWD surveyed by the studies available for review. In addition, 40% of the PLWD surveyed showed raised symptoms of anxiety. Anderson et al (2002) carried out a meta-analytic review to look for an association between anxiety and poor glycaemic control in people with Type 1 and 2 diabetes. In the studies that determined anxiety using diagnostic interview (though not self-report measures) anxiety was found to be significantly associated with hyperglycaemia.

Estimates of the prevalence of depression in PLWD vary but all suggest that it is more prevalent than in the non-diabetic population. Gavard, Lustman & Clouse (1993) estimate that depression affects one in five of PLWD, which is around three times the rate in the general population. In addition, they found evidence that approximately 40% of PLWD whilst not clinically depressed have significantly elevated levels of depressive symptomatology (Gavard et al, 1993). In a review of the evidence for a relationship between depression and diabetes, Talbot & Nouwen (2000) conclude that in both forms of diabetes depression has a higher recurrence rate and depressive episodes last longer than for people without diabetes.

A meta-analytic review by Lustman et al (2000) showed that depression was significantly associated with hyperglycaemia in both Type 1 and 2 diabetes. Ciechanowski, Katon, Russo & Hirsch (2003) found that depressive symptoms were

associated with reduced adherence to self-care behaviours such as exercise and diet recommendations in people with Type 1 and 2 diabetes. Furthermore, depression was found to be significantly associated with the complications of diabetes (diabetic retinopathy, nephropathy, neuropathy, macrovascular complications and sexual dysfunction) in both types of diabetes (De Groot, Anderson, Freedland, Clouse, Lustman, 2001). Zhang et al (2005) conducted a longitudinal study and found that the presence of severe depressive symptoms significantly raised the risk of mortality in people with Diabetes in the USA (the same pattern not being found in the non-diabetic population). In summary, the presence of depression negatively affects self-care in PLWD and is a serious risk factor for poor physical health outcomes.

It is not clear whether there is a raised incidence of eating disorders (e.g. bulimia nervosa and anorexia nervosa) in people with diabetes (DeVries, Snoek & Heine (2004). However, eating disorders in PLWD are associated with persistently poor glycaemic control and early progression to diabetic complications in particular retinopathy (Rydall, Rodin, Olmstead, Devenyi & Daneman, 1997). Under-dosing of insulin is a well recognised method of weight control in young women with Type 1 diabetes which contributes to poor glycaemic control (e.g. Bryden et al, 1999).

DeVries et al (2004) comment that no distinct psychological profile has yet been linked to persistent poor glycaemic control by research evidence. However, some researchers have investigated whether differences in personality and attachment style affect people's ability to self-care in diabetes. Mazze, Lucido & Shamoon (1984) found no relationship between personality types and level of glycaemic control. However, Lustman, Bradley & McGill (1991) found a significant difference in

glycated haemoglobin between people with extreme personality features and those with average personality profiles (measured using Cloninger's Tridimensional Personality Questionnaire). Ciechanowski et al (2004) found that PLWD with dismissing attachment style (characterised by a deactivation of the attachment system and minimal reliance on others in stressful situations) did significantly less exercise, less foot care, were more likely to smoke and were less likely to take prescribed oral hypoglycaemic medication compared to other attachment styles. These outcomes appeared to be mediated by the relationship between the patient and healthcare provider. Turan, Osar, Turan, Ilkova & Damci (2003) also found a significant relationship between dismissing attachment style and worse self-management of diabetes. In addition, they found that dismissing attachment style was associated with coping strategies of avoidance and passive resignation which they believed were mediating the poor self-care outcomes in this group.

In concluding their review of interventions to improve self-management in diabetes, Steed et al (2003) comment that the relationship between adherence to self-management behaviours and well-being in diabetes is unclear. On the basis of existing research it could equally be argued that better self-management leads to better psychological well-being or that improved psychological well-being leads to better self-management of diabetes. Steed et al (2003) suggest that further research should be carried out to investigate this relationship as better understanding of it would help clinicians target their interventions for PLWD who have self-management problems.

In summary, the self-management of diabetes has been shown to be adversely affected by the presence of psychological problems (eating disorders, depression, anxiety disorders). Some authors hypothesise that sub-clinical levels of psychological distress (e.g. worry and low mood) might also be obstacles to effective self-management of diabetes. In addition, people's attachment and personality type impact their level of self-care. As it is clear that psychological distress can be a barrier to self-management of diabetes, interventions which target psychological distress in diabetes will be reviewed in addition to those which aim to improve self-management.

Evaluation of Systematic Reviews

Norris, Engelgau & Narayan (2001)

Norris et al (2001) set out to review the effectiveness of self-management training for people with type 2 diabetes by evaluating relevant RCT's from 1980-1999. Seventy-two studies met their criteria and were reviewed. Norris et al (2001) noted much heterogeneity of methodology, interventions, length of follow up and patient characteristics. They also describe many methodological difficulties with the studies they found; none of the studies fulfilled all the Cochrane definitions (1994) for the absence of bias in RCTs. Internal validity of these studies is threatened by the lack of blinding of researchers or participants to study groups. In many cases, the randomisation method was not elucidated and it seemed that in some trials participants or researchers were able to influence assignment to treatment or comparison condition. There were often high-drop out rates noted and the representativeness of the sample to the study population was often not reported.

Study participants were often inadequately described and sometimes the same professionals were involved in delivering the comparison and active intervention, and unintended contamination of the control group occurred. The majority of the studies compared basic care to a more intensive intervention, without controlling factors like amount of contact time with healthcare providers.

The validity and reliability of the outcome measures was sometimes questionable and generally outcomes were measured using self-report data rather than objective measures of behaviour, making it difficult to tell if changes in behaviour were real or a measurement artefact. For example, self-reported behaviour change may not reflect actual changes in behaviour but could be due to social desirability effects (Michie & Abraham, 2004). In addition when using self-report measures it is unclear if behaviour has actually changed (alpha change) or whether a response shift has occurred e.g. participants have re-calibrated the measurement scale (beta change) or whether they have re-conceptualised the behaviour (gamma change), (Michie & Abraham, 2004).

Important mediating factors e.g. motivation, self-efficacy, were often not measured leaving it unclear how the intervention had worked. The interventions themselves were frequently not well enough described to determine which behavioural theories and techniques were most relevant to the outcomes being measured. These methodological caveats made it difficult to draw firm conclusions about the effectiveness of the interventions they reviewed or to answer the supplementary questions about which techniques worked and how. Michie & Abraham (2004) point

out that, even if a methodologically flawed RCT appears to be effective, the intervention will need further testing to confirm its effectiveness.

However, Norris et al (2001) did make a number of generalisations from the literature reviewed. This paper is concerned with outcomes of self-management behavioural change and reduction of psychological distress so Norris et al's findings concerning these outcomes have been paid particular attention. The main self-management behaviour which the studies measured was self measurement of blood glucose (SMBG). Five studies showed a significant increase in SMBG following a variety of education interventions but none of them followed up participants for longer than six months, leaving it unclear how long this behaviour change persisted. Three studies found an increase in SMBG following their skills teaching interventions but no corresponding improvement in HbA_{1c}.

Some interventions sought to improve "lifestyle behaviours" which contribute to self-management in diabetes. Of the 13 studies seeking to improve diet in Type 2 diabetes, 11 showed improvements in dietary behaviours whilst two did not. Nine studies attempted to increase PLWD's level of physical activity, only four achieved this. Norris et al (2001) were unable to find out from the papers which factors had contributed to success in physical activity changes.

Norris et al (2001) found that increased knowledge (a common goal of the interventions) was not consistently correlated with improved glycaemic control. Seven studies showed increased knowledge and improved glycaemic control, but two found improved control with no change in knowledge, whilst eight demonstrated

increased knowledge and no significant improvement in glycaemic control. Collaborative education interventions were more likely to have positive short term effects on glycaemic control than didactic interventions. Amongst the studies reviewed by Norris et al (2001) which used glycaemic control as an outcome measure, very few followed up participants longer than one year and those that did showed mixed effects. Studies with follow-up times of less than six months showed greater effectiveness than those with longer duration follow-up. The question of how effective self-management interventions for Type 2 diabetes in the longer term remains open.

Norris et al (2001) surmise that factors other than knowledge are required for long term behavioural change in diabetes self-management. They propose that a minimum threshold of diabetes knowledge is needed but that changes in personal attitudes and motivations are more effective than knowledge at improving metabolic control in Type 2 diabetes. Curiously, even by 2004 DeVries et al were unable to find any empirical data on level of motivational problems in PLWD with poor glycaemic control.

Only five studies reviewed by Norris et al (2001) examined psychological outcomes (three of which concerned quality of life and so will not be considered here). One study taught problem solving skills which were found to increase; however, there was no difference in HbA_{1c} levels at six month follow-up. The other was a didactic information giving intervention which showed no difference in depression scores and reduced anxiety at four weeks follow-up. In addition three studies taught coping skills and used support groups, two of them showed improvement in glycaemic

control. The intervention finding no significant change in HbA_{1c} used cognitive behaviour therapy (CBT) techniques and relaxation training in addition to coping skills training and Norris et al (2001) do not discuss why it may have been unsuccessful. From Norris et al's review there appears to be a lack of studies from 1980-1999 including psychological outcome measures or a clearly defined psychologically informed rationale for behaviour modification interventions.

Steed, Cooke & Newman (2003)

Steed et al (2003) set out to review the impact of interventions (which they categorised as principally educational, self-management or psychological) in Type 1 and 2 diabetes on psychosocial outcomes (e.g. depression, anxiety, adjustment, quality of life). They explicitly determined the components of the interventions they reviewed (which should prove helpful in answering questions about which interventions worked and how they worked). In agreement with Norris et al's assertion that a certain amount of diabetes knowledge is necessary, the most common component of the interventions Steed et al (2003) reviewed was education (present in 75% of studies). Thirty-six studies published from 1980-2001 met their criteria and were reviewed. They chose to review pre- post designs as well as RCTs (64% of the studies were RCTs) this paper will just consider the RCTs.

Steed et al comment that 75% of the studies they reviewed were published since 1992, reflecting a shift from only reporting glycaemic control and knowledge outcomes, to a broader range of measures including psychological factors and quality of life (which is outside the scope of this paper). In contrast to Norris et al, they

found that reporting of demographic information and attrition rates was high amongst the studies they reviewed. However, Steed et al still made mention of a number of methodological issues: many of the RCT's were underpowered (possibly explaining why the pre-post designs more consistently showed positive changes on psychological outcomes than the RCTs). The studies were limited by inadequate descriptions of the interventions making replication of the studies difficult. This also made it difficult for Steed et al to accurately code the components of the interventions. In addition they were unable to fulfil their aim of examining the efficacy of the intervention components because of overlap between the components used in different types of interventions and because many components were used in each intervention.

Only five of the studies measured psychological well-being as opposed to negative psychological states like low mood or anxiety. One of them found significant improvement in positive and negative aspects of well-being. This was a self-management intervention using education, group discussion and skills training components. The other four studies found no change in well-being relative to controls or over time. Only one RCT assessed emotional adjustment but it found no difference between a self-management and education intervention.

Six RCT's concerned depression with four of them showing improvement in comparison to standard care or education. One was an education intervention the other three used a variety of psychological techniques. All three included some aspects of cognitive therapy, with two of them additionally adding techniques from

behaviour therapy, relaxation and problem solving approaches. The two ineffective interventions used self-management and education interventions.

Seven RCT's concerned anxiety but only two (an education programme and an intervention using psychological stress management techniques) showed any improvement in anxiety relative to controls. The ineffective studies included an education intervention self-management intervention, two interventions using relaxation techniques and one trial using cognitive therapy.

Overall Steed et al (2003) concluded that the use of both self-management and psychological interventions in diabetes care are justified by the literature. However, they found no reason to continue the use of purely didactic education programmes because compared to self-management and psychological interventions these lacked efficacy for improving glycaemic control and in addition had no added beneficial effect on psychosocial outcomes. They were not able to determine which components of the interventions reviewed were effective at improving self-management and/or reducing psychological distress in diabetes because the studies had not been designed with this in mind.

Ismail, Winkley & Rabe-Hesketh (2004)

Ismail et al (2004) undertook a meta-analysis of psychological therapies aimed at improving glycaemic control in Type 2 diabetes. They reviewed 25 RCT's published or unpublished from 1983 to January 2003. It was not clear whether the unpublished trials had been peer reviewed and as such they may have been less methodologically sound than the published trials.

Ismail et al found no RCTs of interventions using a psychodynamic or interpersonal model of therapy and they seem not to have included systemic/family therapy based interventions in their search strategy. The majority of the interventions were derived from the cognitive behavioural therapy (CBT) model or its component techniques. Unlike Steed et al (2003) they did not attempt to identify the components of the interventions they reviewed beyond categorising the main psychological model employed. In addition, it might have been helpful if they had separated the more explicitly cognitive therapy interventions from those using just behavioural techniques such as relaxation. Ismail et al also grouped motivational interviewing (MI) interventions with generic counselling techniques, which is surprising given that MI uses counselling and behavioural techniques to enhance motivation for behaviour change whilst the goal of counselling is less pre-defined.

Two methodological issues were noted by Ismail et al: many of the studies had small sample sizes which could have impacted their ability to detect the effect they were investigating. Secondly, most of the studies originated in the USA and funding issues there could have resulted in a focus on group interventions leaving the potential of individual interventions relatively untapped.

Nine studies assessed weight change but psychological therapies were associated with a non-significant increase in weight. Four studies pertained to specific psychological problems (depression, binge eating, stress) and the psychological therapies reviewed by Ismail et al were found to significantly reduce psychological distress.

Their meta-analysis of the effect of psychological therapies on HbA_{1c} incorporated twelve studies, all but two involved CBT, and only four of which were delivered individually. The participants of the twelve studies, whilst all having Type 2 diabetes, were heterogeneous ranging from a general group of patients, through those with persistent poor glycaemic control to those with specified difficulties including obesity, binge eating and depression. Summarising data from all these diverse PLWD for the meta-analysis and not providing a narrative systematic review limits the papers' ability to communicate which interventions are effective for which members of the Type 2 diabetes population. Also, given that ten of the studies involved CBT it might have made more sense to conduct the meta-analysis just on these studies to give an indication of the specific effect of CBT techniques on glycaemic control in Type 2 diabetes. However, Ismail et al (2004) report that psychological therapies resulted in significantly better glycaemic control approximating to an absolute difference of 0.76% in glycated haemoglobin. This effect was large enough to reduce the risk of development and progression of diabetic complications.

Extension of Existing Systematic Reviews

To recap, 8 RCT's of self-management interventions and/or interventions concerning reduction of psychological distress in people with Type 1 and 2 diabetes from 2001 onwards which reported behavioural and/or psychological outcomes were identified. Three of the studies targeted Life-style changes: Keyserling et al (2002) and Clark, Hampson, Avery & Simpson (2004) both focussed on increasing physical activity & reducing the amount of fat consumed); Glasgow, Toobert, Hampson, Strycker (2002)

focussed on changes in diet. One evaluated a brief problem orientated psychotherapeutic intervention (Didjergeit, Kruse, Stuckenschneider & Sawicki, 2002). One was a self-management intervention (Steed et al, 2005) and one aimed to empower patients in medical consultations (Williams et al, 2005). Finally two studies evaluated systems for managing mental health problems in diabetic patients (Katon et al (2004); Pouwer, Snoek, Van Der Ploeg, Ader & Heine (2001).

Keyserling et al (2002)

Keyserling et al (2002) assessed the effects of a programme to increase daily moderate physical activity and reduce fat intake. The main methodological considerations were that the healthcare providers were not blind to the status of their patients and the patients were also aware of the arm of the study they were assigned to. The accelerometer measure of daily activity may not have been reliable enough to gain accurate results. Finally the participants were all African-American women with Type 2 so the generalisability of this study to the wider diabetic population may be limited. Keyserling et al (2002) used three conditions including a contact time matched education control condition, just clinic and clinic plus community support levels of their intervention. The intervention was well described and was said to be based on behaviour change theory. The main psychological components seem to have been goal setting, provision of social support and reinforcing the attainment of behavioural goals. The main findings of the study were that the two active intervention groups made modest increases in physical activity at 1 year follow-up. The clinic and community intervention group had significantly higher physical activity than the control group. No differences in fat intake were found and all three group gained weight (non-significantly). This was not reflected in any significant

changes in HbA_{1c} levels or blood cholesterol. Well-being was also measured and had increased in all the groups at 1 year follow-up. This behaviour therapy based approach has resulted in some gains in physical activity (though not glycaemic control) but only when combined with the highest level of follow-up contact from healthcare professionals.

Clark et al (2004)

In a UK study, Clark et al (2004) also aimed to increase physical activity and decrease fat intake in people with Type 2 diabetes though this was a mixed group with Body Mass Indexes (BMI) >25. They compared a well described motivational interviewing intervention with telephone contact with usual care, which was not described but presumably was not matched for contact time with healthcare professionals. Other methodological issues were that no power calculation was reported and the therapists and patients were not blind to treatment condition. The intervention resulted in significant reductions in fat-related eating habits and waist circumference at 1 year for the intervention group. In addition, the intervention group maintained their BMI whilst the comparison groups increased at 1 year. However, no significant differences in activity level, HbA_{1c} levels or blood cholesterol were found. Motivational interviewing shows potential for helping people with Type 2 diabetes to change their dietary behaviours.

Glasgow et al (2002)

Glasgow et al (2002) conducted an implementation study of an intervention (whose effectiveness had already been established with an RCT) in the USA. The

intervention used computerised dietary goal setting, self-help and MI sessions to improve people with Type 2 diabetes dietary behaviours. Glasgow et al (2002) compared different levels of community resources and telephone support in addition to this intervention. No power calculation was reported, the randomisation procedure was not reported and neither was the extent to which researchers, healthcare professionals and patients were blinded to treatment condition. Glasgow et al (2002) report that all conditions showed a significant improvement for dietary behaviours and HbA_{1c} levels at 1 year follow-up.

Didjurgeit et al (2002)

In Germany, Didjurgeit et al (2002) compared a time limited theory driven problem orientated psychotherapeutic intervention with wait list controls (contact time was not controlled for) in patients with Type 1 diabetes with microvascular complications and persistent psychological problems. The intervention was clearly described and the model was referenced rather than explained. The intervention was delivered individually by the same therapist who had supervision but did not follow a protocol so the trial would be difficult to replicate. No power calculation was reported and only 46 patients in total were seen so it is possible that the study was underpowered. The researcher was blind to treatment allocation although the therapist and patients were not. The length of follow-up at six months was shorter than in other studies reviewed. One of the main outcome measures was self-rated problem scores and these were found to significantly reduce as did HbA_{1c} levels although depression scores did not differ between groups. It is interesting to note that this psychotherapeutic approach addressing patient specified difficulties has resulted in a reduction in HbA_{1c} levels.

Steed et al (2005)

In another UK trial Steed et al (2005) devised a self-management programme for people with Type 2 diabetes and microalbuminuria (an early sign of renal complications). This was compared to standard treatment which was not described so presumably contact time with healthcare professionals was not controlled for. The intervention was based on ideas about increasing self-efficacy and Leventhal's Common Sense Model of Illness Representations (Leventhal, Leventhal & Contrada, 1998). A manual and training in the intervention are available from the authors which allows for replication. The psychological elements of the programme were collaborative psychoeducation, goal-setting, discussion of how thoughts shape behaviour and problem solving to overcome barriers to self-care behaviours. The group facilitators and patients were not blind to treatment allocation and the follow-up was only three months, so the longer term effect of the intervention is unknown. The results were encouraging the intervention group had significantly improved blood glucose monitoring, foot care, more exercise, better diet and fewer of them were smoking than the comparison group at three months. HbA_{1c} levels did not differ however nor did measures of anxiety and depression between groups at three months. However, it can be difficult to assess the 'penetration' of self-management interventions, although they are well-liked by participants who attend. There was a 51% take up for the UCL-DSMP trial (Steed et al., 2005). Participation for diabetes group interventions ranges from 32% to 100% in USA (Glasgow et al., 1996). Such groups are however, unlikely to engage those patients who are most at risk for the development of complications; for instance the 'drop outs' in UCL-

DSMP trial were more likely to have higher HbA_{1c} results at baseline than those who completed the intervention.

Williams et al (2005)

In the USA, Williams et al (2005) aimed to improve glycaemic control in Type 2 diabetics by increasing patient involvement in medical appointments. The theory behind the intervention was not reported. The intervention was adequately described and consisted of giving accurate information on patients level of health and the risk factors in diabetes facilitating the generation and rehearsal of questions for their doctor. The comparison condition consisted of time matched watching of diabetes education videos. It is unclear what the mechanism for change in diabetic control was hypothesised to be. Methodological problems were that the randomisation procedure was not reported and no power calculation was made. The findings of the study were that the intervention group asked more questions in their consultations but there was no difference in HbA_{1c} levels between the groups at 1 year.

Katon et al (2004)

In the USA Katon et al (2004) conducted an RCT to find out whether enhanced management of depression in depressed people with diabetes would result in better glycaemic control and reduced depressive symptomatology. The comparison group was encouraged to take anti-depressant medication at outset and adherence was measured. However, the nature of any mental health care they were receiving was not measured and could have been a confounding factor. The intervention consisted

of problem solving training (which had been used in primary care with depressed patients) and social support from nurses and/or antidepressant medication as patients wished; psychiatric consultation could also be added if patients showed no improvement. The nature of the intervention and its theoretical underpinnings were not well explained and the study was unblinded. The intervention group's adherence to antidepressant medication increased and they showed a significant reduction in depression severity; however, no difference in HbA_{1c} levels were found between the groups.

Pouwer et al (2001)

In a Dutch study, Pouwer et al (2001) used an RCT to investigate whether explicit monitoring of well-being (and referrals to psychology if indicated) by diabetes specialist nurses (DSN) would make any difference to mood and glycaemic control. In the comparison group patients received standard care when enquires about well-being and referrals to psychology were possible but not carried out as standard. Who saw a psychologist and how they were treated by them remain a hidden aspect of this study. The theoretical underpinnings of the study are not reported. As the same DSNs conducted both conditions it is possible that some contamination of conditions occurred. No attempt to control for the increased contact time with the intervention group was made. At 1 year follow-up the monitored group had significantly better well-being, mood, energy and mental health scores. They were more likely to have been referred to psychology. However, the groups did not differ for HbA_{1c} levels.

Conclusions

Only two of the studies showed improved glycaemic control (Didjergeit et al, 2002 & Glasgow et al, 2002) which used a psychotherapeutic approach and a mixed intervention using MI and social support. Studies using MI showed improvement of dietary behaviours (Glasgow et al, 2002) though not additionally physical activity levels (Clark et al, 2004). Interventions based on behaviour change theory were successful in increasing physical activity though not at bringing dietary change (Keyserling et al, 2002). The study which used a theory driven approach to self-management improved a wide range of self-care behaviours (Steed et al, 2005). The two studies which addressed monitoring and enhancing mental health outcomes in PLWD improved mental health outcomes though not glycaemic control (Katon et al, 2004; Pouwer et al, 2001).

Discussion

The main methodological weakness of this review is that its search may have been too narrow, it only reports the literature on adults, English language RCTs, and did not search grey literature (e.g. theses, and studies published on the internet). However, this should be balanced against the reliability issues with non-RCTs (which cannot demonstrate causation) and grey material (which are not stringently peer reviewed). In addition, a narrative approach to evidence synthesis was used (rather than a meta-analytic one) due to the wide variety of interventions and outcomes reviewed. However, on balance this paper has been able to effectively address the research aims.

Have the Questions Been Answered?

Overall, this paper has had more success in answering the first two questions than the supplementary ones. It has been possible to describe some of the obstacles to effective self-management in diabetes and to discover which interventions have been found to improve behavioural outcomes and or relieve psychological distress in diabetes. Success has been limited in answering how the interventions work.

The systematic reviews revealed many methodological concerns but were able to offer some answers to the question of which interventions improve self-management and/or decrease distress in diabetes. Norris et al (2001) review lots of methodological flaws in the literature, and few of the studies included psychological outcomes. The lack of reported detail of the interventions, or the theories they were based on, made it impossible to work out which components of interventions were effective in improving self-care and decreasing psychological distress.

Diabetes knowledge was not found to be consistently correlated with improved glycaemic control by Norris et al (2001). In their review, Steed et al (2003) went further concluding that didactic education programmes lacked efficacy for improving glycaemic control (and psychological outcomes) compared to self-management and psychological interventions. Fosbury et al (1997) discuss why this might be, they observe that educational interventions tend to assume that decisions to perform self-care behaviours are based on rational processes. However, decision making in general is influenced by unconscious and emotional processes. Fosbury et al (1997) advocate focussing on the psychological and emotional processes which affect diabetes management in order to enhance self-care in diabetes. Despite healthcare provider recognition of a high level of psychological distress in PLWD and its impact on their ability to self-manage, few PLWD were found to be receiving psychological support (9% of people with Type 1 and 12% of those with Type 2 diabetes had received psychological treatment in the past five years) (Peyrot et al, 2005). Psychological input might be expected to reduce their distress and improve their diabetes self-care.

Steed et al (2003) found less methodological issues than Norris et al (2001) with the literature and tried to categorise the intervention components of the studies they reviewed. They were hampered in this by the design of the studies which used many different components in each intervention or showed overlap with other types of intervention. Hence, it was not possible to examine the efficacy of the intervention components. Ismail et al's (2004) meta-analysis of psychological therapies for people with Type 2 diabetes showed the potential of such approaches to prevent diabetic

complications. From this it can be stated that psychological therapies (especially those based on CBT) are effective at improving glycaemic control. However, as Ismail et al (2004) did not set out to examine which particular components of the interventions were effective and how they brought about changes in self-management and psychological distress remains unanswered.

The extended review found that amongst recent studies a self-management approach, a behaviour change theory based approach and motivational interviewing (MI) showed promise in enhancing diabetes self-management and psychological well-being. MI uses supportive, empathic counselling and behaviour change techniques to establish and enhance a person's motivation for behaviour change. One of the reasons MI might be an important intervention to use with PLWD who are not adopting the recommended self-management practices is because the technique establishes what the person knows about diabetes and how aware they are of the risks to their own health from continuing with their current diabetes management style. Skinner (2004) reports that only 22% of PLWD in the UK believe that it will have much effect on their health and fewer still (only 9%) are aware that their life will be shorter due to diabetes. This demonstrates that PLWD often have little understanding of the personal relevance of diabetes to their health which is likely to reduce their motivation to effectively self-manage their blood glucose levels.

Future Directions in Interventions in Diabetes Care

It appears that in diabetes care a problem with effective self-management of diabetes has been recognised and pre-existing interventions to increase positive health behaviours have been applied. In many cases this has occurred with little attempt to

understand why PLWD struggle to manage their diabetes. It might perhaps have been helpful to consider the health psychology literature on coping strategies in chronic illness in relation to the observation of poor adherence to self-management advice in PLWD.

Coping strategies refer to the ways (both behavioural and psychological) that people utilise to master, tolerate or reduce stressful events. One distinction which is often made in the coping literature is between active and avoidant coping. Active coping strategies are behavioural or psychological responses which change the nature of the stressor itself or how the person thinks about it. Avoidant coping meanwhile results in activities such as alcohol use or mental strategies like withdrawal or choosing not to think about the stressor. In general active coping is associated with better health outcomes than avoidant coping (e.g. Holahan & Moos, 1987). When coping style has been investigated in adolescents with diabetes it has found to be associated with glycaemic control (Seiffge-Krenke & Stemmler, 2003). They followed up adolescents with diabetes for four years and found that those exhibiting stably good metabolic control over that period also utilised less avoidant coping strategies in dealing with minor stressors than those adolescents found to have stably satisfactory or poor glycaemic control.

The trial and error application of techniques taken “off the peg” from other health conditions or areas of psychology to diabetes has met with some success. It has been established that information alone does not lead to improved self-management of diabetes. It has been shown that psychological interventions (particularly those

calling themselves CBT) bring about significant improvement in diabetic control. However, it is unclear how and why the CBT approaches have worked.

It has also been shown that PLWD have higher rates of psychological distress and diagnosable mental health problems. This appears to be a complex bidirectional relationship where psychological distress raises the chance of developing diabetes (e.g. in depression and psychosis) and coping with diabetes seems to increase psychological distress. Despite this it is unclear what the relationship between psychological distress and self-management difficulties is. It would make sense to conduct studies to try to understand whether treating mental health problems and reducing psychological distress in PLWD brings about an enhancement of their physical health and diabetic control. In addition having detected this unmet need it would be unethical not to offer PLWD mental health care. An awareness of the mental health needs of PLWD is increasing in diabetes clinics although this is not always matched by access to psychologists and other mental health professionals.

It is also possible that psychological distress alone is not the only obstacle to effective self management of diabetes. For example PLWD who have psychological well-being could still have poor diabetic control. An understanding of the many factors including social, developmental, physiology, thoughts, emotions and behaviours which obstruct good self-care and maintain difficulties with self-management in PLWD is yet to be developed. It could be argued that this is a necessary prerequisite for designing and testing out interventions to enhance self-management of diabetes.

David Clark belongs to a research group who develop new CBT treatments particularly for anxiety disorders, in a 2004 paper he describes the process which their research takes. This differs substantially from the process which has evolved in the field of diabetes care. His research group have found that simply applying a treatment from one condition to another is not necessarily successful. This seems to be because each anxiety disorder has a characteristic cognitive bias associated with it. As an example many people with panic disorder make catastrophic misinterpretations of body sensations for instance that their pounding heart means they are having a heart attack and will die. It is not yet known whether PLWD who have persistently poor glycaemic control and or high psychological distress also have distinct cognitive biases which might explain their difficulties. However, this might prove an important research arena.

Having an understanding of the psychological processes underpinning a psychological problem has been found to be insufficient to explain why the psychological problem remains. In the case of panic disorder a sufferer might have 30,000 panic attacks before entering treatment, in each one they would believe that they were dying and yet they survived. However, this does not alter their belief that the panic attack is a heart attack. Another member of the group, Paul Salkovskis, proposed that because they engaged in safety-seeking behaviours (e.g. sitting down, taking deep breaths) they attributed their not dying to their actions meanwhile their belief that they had experienced a serious cardiac event continued. This demonstrates that understanding what maintains the cognitive biases is also very important to making sense of psychological difficulties and then being able to create effective

treatments for them. It is possible that avoidant coping strategies maintain poor self-management of diabetes.

Clark (2004) elucidates the stages of developing new treatments employed by his research group:

- i) collecting theories and clinical data on the problem. For a cognitive therapy intervention hypothesise about the core cognitive abnormality.
- ii) Construct a theoretical account which explains why the cognitive abnormality does not self-correct (formulate your understanding of the problem including the maintaining factors)
- iii) Test the hypothesised maintaining factors in rigorous experimental studies
- iv) Develop specialised cognitive treatments which aim to reverse the empirically validated maintaining factors. Clark points out that there is a gap between a promising cognitive theory and a successful cognitive treatment because cognitive theories do not directly suggest treatment procedures.
- v) Test the efficacy of the treatments in randomised controlled trials (RCTs)
- vi) Use dissemination studies to make the treatments more widely available

Another approach to designing effective interventions to help PLWD improve their self-management of diabetes would be to follow the strategy above. A simplified version would be to start by developing an understanding (formulation) of the problem and then use that formulation to guide hypotheses about where the new treatment should intervene and how.

Conclusions

Interventions to improve self-management comprise the main focus of treatment for diabetes and the efficacy of such efforts are dependent upon the motivation and ability of the individual and the systems in which they live. More than half of PLWD do not practice adequate self-care of their diabetes placing them at increased risk of experiencing diabetic complications and mortality prematurely (Peyrot et al, 2005). Whilst there is a great deal of evidence that psychological distress in its many guises negatively affects self-management of diabetes the main finding of this paper has been to demonstrate that relatively little is known about how and why this is the case. It appears that by and large interventions to help PLWD improve their self-management have taken “off the peg” interventions from other conditions and applied them to diabetes. This review proposes that a more targeted approach, beginning with researching and understanding why PLWD might struggle to perform self-care behaviours, is more likely to yield an effective and theory driven intervention.

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Part 2 (Empirical Paper)

EVALUATION OF A MINDFULNESS-BASED THERAPEUTIC APPROACH FOR PEOPLE LIVING WITH DIABETES

Abstract

The study describes the first stage of evaluation of a new mindfulness-based intervention for people living with diabetes who have difficulty self-managing their condition. The main purpose of the study was to find out whether the intervention was acceptable to the participants, whether it caused any negative side-effects and to ascertain participants' views of perceived benefits and the mechanisms via which these were effected. Supplementary aims were to establish whether the proposed methods to evaluate the efficacy of the intervention were valid and whether the intervention was feasible within an NHS context. Data on a case series of 9 individuals who received the intervention was collected. Pre, weekly and post self-report measures and post qualitative interviews were collected. Results demonstrated that the intervention was feasible within the clinic setting, was considered acceptable by participants, and that participation was associated with benefits (such as increased acceptance of diabetes and self-care tasks, performing more self-management tasks, feeling less negative emotions or relating to them differently, improved coping with pain), finally no negative side-effects were reported.

Introduction

Diabetes

In the UK, around 1.3 million people have been diagnosed as having diabetes (DOH, 2002). Diabetes occurs when the body cannot process glucose properly and blood glucose levels become raised. This may be because not enough insulin (a hormone involved in glucose regulation) is produced. This occurs in Type 1 diabetes, which is an autoimmune disease usually diagnosed in childhood or adolescence. It may also happen when the body has become insulin resistant, as in Type 2 diabetes which often has a slow onset in adulthood; over three quarters of people with diabetes have this form of it (Diabetes UK, 2003¹). Diabetes is becoming increasingly common and has a significant effect on the people who have it and their families. As a chronic and worsening condition it is also of great concern to healthcare planners.

Self-Management of Diabetes

Diabetes has a wide ranging impact on people's lives, affecting their physical, material and psychological well-being. People with diabetes are recommended to make adjustments to their lifestyle and to regulate their blood glucose levels. The process of blood glucose adjustment must be carried out throughout each day based on what is consumed and the person's activity levels. People with diabetes therefore have the onerous task of managing their own blood glucose levels, this is usually referred to as "self-management" or "self-care". Glycosylated haemoglobin (HbA_{1c}) level is often taken as a measure of adequate self-management as it gives an indication of glycaemic control over the previous three months.

Many people cope with the demands of managing their diabetes extremely well. However, a significant number of people living with diabetes (PLWD) do not manage to keep their blood sugar levels in the recommended range. This can hasten the onset and progression of diabetic complications, which include blindness, kidney failure, heart disease and stroke (Diabetes UK, 2003²). Poor self-management is commonly cited as the major determinant of premature progression to diabetes-related complications (Fosbury, Bosley, Ryle, Sonksen, Judd, 1997). Whilst psychological factors have been implicated as making a major contribution to this more recent reviews have suggested that poor diabetes self-management is more complex than originally thought ((DeVries, Snoek & Heine (2004). Several factors that are beyond conscious individual control mitigate against being able to maintain good-enough control of blood glucose levels. Factors that have been empirically demonstrated to make the task of self-management more difficult include physiological factors such as the degree of insulin resistance, genetically determined rates of glycolation, and the impact of stress upon glucose metabolism (Riazi, Pickup, Bradley; 2004). Therefore, PLWD have to grasp the complex health message that the occurrence of diabetic complications is partly but not completely within their control (Parry, Peel, Douglas & Lawton; 2006).

PLWD's level of performance of the recommended self-management tasks tends to be low (Steed et al, 2005). To investigate how successful PLWD were at managing their diabetes the Diabetes Attitudes Wishes and Needs (DAWN) Study (Peyrot et al, 2005) used self-report questionnaires with 5104 randomly selected PLWD and 3827 healthcare providers in 13 countries worldwide. Their results showed that only 46%

of people with Type 1 and 39% of people with Type 2 diabetes achieved complete success in a minimum of two-thirds of their self-management domains. Despite the sizable proportion of PLWD who are at risk of developing diabetic complications (or dying early as a consequence of them) the reasons for poor self-care in diabetes are complicated and not fully understood.

The Impact of Psychological Factors on Self-management in Diabetes

It has been shown that many PLWD have poor psychological well-being, for example, 41% of the PLWD surveyed by the DAWN study were experiencing poor psychological well-being. Rubin & Peyrot (2001) hypothesise that PLWD may experience sub-clinical levels of emotional distress for a number of reasons: the daily demands of diabetes self-management, living with the reality or fear of diabetes complications and as a possible consequence of the physical fluctuations in blood glucose level.

It has been demonstrated that psychological problems have a negative impact on self-management in diabetes. For instance, a case study of people with poorly controlled Type I diabetes found that despite the majority of participants not having diagnosable psychiatric illness, they did have a range of emotional difficulties that adversely affected their ability or willingness to self-care (Milton, 1989). Furthermore, Peyrot et al (2005) also found that between 66-74% of the healthcare providers believed that psychological problems adversely affected their patients' adherence to their self-care regimen. Despite this recognition of the problem, Steed et al (2003) comment that the relationship between adherence to self-management behaviours and well-being in diabetes is unclear. They suggest that on the basis of existing research it could

equally be argued that better self-management leads to better psychological well-being or that improved psychological well-being leads to better self-management of diabetes.

In addition to having higher levels of psychological distress, the prevalence of diagnosable mental health problems are higher in PLWD. Psychiatric conditions have been shown to be associated with poor diabetic control. The prevalence of anxiety disorders are higher in PLWD (Grigsby, Anderson, Freedland, Clouse & Lustman, 2002) and anxiety was found to be significantly associated with hyperglycaemia (raised blood glucose levels). Depression is also more prevalent amongst PLWD and its course seems to be more severe. In both forms of diabetes depression has a higher recurrence rate and depressive episodes last longer than for people without diabetes (Talbot & Nouwen, 2000). Ciechanowski, Katon, Russo & Hirsch (2003) found that depressive symptoms were associated with reduced adherence to self-care behaviours such as exercise and diet recommendations in people with Type 1 and 2 diabetes. It is not clear whether there is a raised incidence of eating disorders (e.g. bulimia nervosa and anorexia nervosa) in people with diabetes (DeVries, Snoek & Heine (2004). However, eating disorders in PLWD are associated with persistently poor glycaemic control and early progression to diabetic complications in particular retinopathy (Rydall, Rodin, Olmstead, Devenyi & Daneman, 1997).

Previous Attempts to Enhance Self-Management in Diabetes

Reflecting this awareness of the magnitude and importance of the problem many interventions aimed at improving self-management in diabetes have been tried. Paper

1 in this volume reviews these attempts, which are summarised here. Steed et al (2003) describe how the interventions have fallen into two main camps: those addressing poor adherence to the lifestyle regimen and those working with mood alteration (for example low mood, anxiety and stress). Interventions aiming to improve adherence have two main forms: basic education programmes and self-management interventions. It has been shown that while knowledge about *how to* manage diabetes is necessary, it is not always sufficient for behaviour change leading to improved clinical outcomes in diabetes (Brown, 1999; Wing, 1996). Clear evidence exists that educational interventions are not effective in either improving glycaemic control or psychological outcomes in PLWD (e.g. Steed et al, 2003). As a result self-management interventions also use techniques such as problem solving and looking at how an individual's beliefs and attitudes towards diabetes may be impacting their self-management style. Attempts to evaluate which components of the existing interventions are effective have been hampered by the fact that they have combined many different components and overlapped with each other in terms of intervention type.

The interventions which work on negative mood states do so mainly using cognitive techniques. Indeed, Ismail et al (2004) do not report on any group interventions which depart from the education, self-management or cognitive models in their meta-analysis of randomised controlled trials (RCTs) of psychological interventions designed to improve glycaemic control in type 2 diabetes. Ismail et al (2004) found that compared to waiting list, usual care, education or attention control groups, cognitive based psychological therapies were significantly better in terms of improved glycaemic control. Encouragingly, the size of the effect was great enough

to reduce the risk of developing or progression of diabetic microvascular complications. Psychological therapies also significantly reduced psychological distress of people with diabetes. However, Ismail et al, point out that it cannot be concluded that cognitive based therapies are the most effective in assisting people with diabetes to manage their blood glucose as they are the only therapeutic models which have so far been evaluated. In addition, it is not yet known which subgroups of patients are most likely to benefit from these types of intervention. It may be the case that cognitive therapy interventions are effective with patients with particular thinking styles but not others or those who are less keen on talking therapies.

It is also unclear to what extent the interventions which claimed to work because of cognitive behavioural therapy (CBT) techniques actually adhered to a strict CBT format. White (2001) makes the observation that, “many practitioners profess to be using CBT when they are in fact using cognitive or behavioural strategies or treatment techniques which are applied in isolation and without sufficient reference to a formulation or as an amalgam with other therapies” (pg 10). This is an important distinction because CBT is based upon empirically supported theories which form the explanation of how the intervention works. In the absence of a clear indication of whether the interventions met criteria for CBT (or any other psychological therapy) it is impossible to say how they worked or which components were required to produce change.

This lack of a clear formulation (understanding of the problems, their causes and maintaining factors) for self-management problems and psychological distress in PLWD makes it difficult to take a first step in designing interventions to help PLWD.

As no such formulation exists what follows is the author and Dr Paul Chadwick's understanding of the problem based on clinical experience with PLWD.

Our Understanding of Self-Management Problems in Diabetes

People with Diabetes have to contend with a very strong discourse of control and responsibility when it comes to their experience of their condition. Since tight glycaemic control can substantially delay the onset of complications medical staff tend to invoke notions of personal responsibility, guilt and shame to encourage patients to establish better control. For example, Parry, Peel, Douglas & Lawton (2006) describe the censure with which medical professionals respond to PLWD who do not appear to be following their self-management advice. The main UK charity for PLWD, Diabetes UK (2006), reinforces the message of personal responsibility in the information it provides. However, as the occurrence of diabetic complications is partly but not completely within their control this can be confusing (Parry et al, 2006).

All this can make PLWD feel that the task of self-management is impossible and when coupled with an awareness of the complications of uncontrolled diabetes can evoke strong fear responses. Some people with diabetes seem to cope with this by engaging in an all-or-nothing struggle to obtain good glycaemic control, all of the time. As the stakes are very high if adequate control of blood sugar is not maintained some PLWD seem to develop black and white thinking about their self-management, which seems to resemble perfectionism. If their blood glucose levels are outside the tightly defined recommended range (regardless of whether this could be explained by factors beyond their personal control) this can be regarded as a personal failure

leading to feelings of guilt, anxiety, low mood and anger. Believing that their overall diabetic control is not 'good enough' can spill into a personal sense of failure and not being 'good enough'. For these reasons the use of avoidant mechanisms of coping are very reinforcing. This can manifest itself in non-attendance at clinic appointments, failure to check blood glucose or monitor diet and the mismanagement of insulin, amongst other things. Basco (1998) in a non-empirical discursive paper sets out the difficulties PLWD face when they are perfectionists and how this can lead to feelings of guilt and avoidance of thinking about diabetes. "Perfectionists tend to equate diabetes control with success. When they are unable to reach a good level of blood glucose control, it feels like failure. This generates negative emotions (e.g., sadness, frustration, anger), all of which serve to reduce motivation. Sally thought she was a failure with regard to her diabetes management, and she felt very guilty. Because she could not keep up, she put her diabetes management "out of her mind." This kept her from having to feel guilty and think about her failure"... "For Sally, as for most perfectionists, when she cannot be completely successful with her diabetes care, she feels like a failure. This leads to giving up the pursuit at least until she can be 100% successful again. When she cannot do it all, she does nothing." Basco (1998).

In general active coping is associated with better health outcomes than avoidant coping (e.g. Holahan & Moos, 1987). When coping style has been investigated in adolescents with diabetes it has found to be associated glycaemic control. Seiffge-Krenke & Stemmler (2003) followed up adolescents with diabetes for four years and found that those exhibiting stably good metabolic control over that period also utilised less avoidant coping strategies in dealing with minor stressors than those adolescents found to have stably satisfactory or poor glycaemic control.

Mindfulness-Based Approaches

Mindfulness is associated with the meditation practices of Buddhism (where it has been evolved and refined to its highest point). Mindfulness (or mindfulness meditation or meditation) can be a difficult concept to define. Mindfulness is easier to gain some understanding of experientially, perhaps the following quote from a traditional meditation teacher will demonstrate this, “Once an old woman came to the Buddha and asked him how to meditate. He told her to remain aware of every movement of her hands as she drew water from the well, knowing that if she did, she would soon find herself in the state of alert and spacious calm that is meditation” (Sogyal Rinpoche, 2002, p.62). One widely quoted definition of mindfulness from a western meditation teacher is, “paying attention in a particular way: on purpose, in the present moment, and non-judgementally” (Kabat-Zinn, 1994, p. 4).

Work by Baer, Smith, Hopkins, Krietemeyer, & Toney (2006) has demonstrated that mindfulness is not simply the renaming of a previously recognised psychological construct, i.e. mindfulness represents a unique combination of facets. Baer reviewed the mindfulness self-report measures of six independent research groups and concluded that mindfulness includes: paying attention to, noticing, observing, or being aware of present-moment experience, with acceptance, willingness, openness, curiosity, interest, kindness, compassion, without judgements or reactivity and acting with awareness and undivided attention (and includes describing, noting or labelling experience). Mindfulness based approaches differ from other models because they assume that the current experience of the individual is valuable in itself and does not need to be altered in order for them to experience well-being. In this way they promote the ability to tolerate distressing emotions, thoughts and images and

physical sensations and the ability to accept current experience as it is. They propose that anyone (no matter how unwell in medical terms) can experience well-being moment to moment by practising the techniques of mindfulness.

Jon Kabat-Zinn's Mindfulness-Based Stress Reduction (MBSR) programme evolved in the USA in the late 1970's (based on Zen Buddhism). It was offered to large (40 participants plus) heterogeneous groups of hospital patients with a mixture of different physical (and additional psychological) problems who were united in not having recovered through standard medical care alone. In this they share some similarity with the study's target population who, despite standard NHS care, continue to face difficulties managing their diabetes. MBSR made great efforts to keep any esoteric aspects of Buddhism out of the programme and to carefully explain any which needed to remain.

It was decided to investigate mindfulness as a potentially useful intervention for PLWD. This is an approach that has not been specifically applied to diabetes before (based on literature searches in 2003 and 2006 which revealed no papers, book chapters, theses on mindfulness or meditation and diabetes care) because the evidence from other chronic health conditions were very favourable. In a review of the health effects of 64 empirical studies of MBSR, Grossman et al (2004) found that it has been applied to populations as diverse as people suffering from everyday stress to cancer patients. The studies typically noted improvement on measures of coping, quality of life, anxiety, depression and medical symptoms (including pain). Only 6 of the studies included in their analysis had an active control condition. An effect size of 0.5 ($p < 0.0001$) for both controlled and uncontrolled studies was calculated; Cohen

(1988) classifies this as a medium effect size, which is typical of psychological interventions.

Mindfulness-based stress reduction (MBCT) is essentially the MBSR programme with the addition of some relevant cognitive therapy techniques. Teasdale et al (2000) conducted an RCT of MBCT and demonstrated that it was efficacious as it significantly reduced the rate of relapse for people with recurrent depression. Teasdale, Segal & Williams (2003) caution against the application of mindfulness as a generic treatment to other disorders without first formulating the problem they seek to treat and how mindfulness could be helpful to people with the disorder. The main rationale for this is that they demonstrated that mindfulness is actually unhelpful in some contexts, it is likely that there are many dimensions of effectiveness underlying the apparently simple concept of mindfulness and mindfulness is derived from a particular “view” of human suffering which implies wider changes that extend beyond meditation practice alone.

Our Understanding How Mindfulness Might Help with Self-Management Problems in Diabetes

Our formulation for the use of mindfulness-based approaches for PLWD (who were experiencing psychological distress and self-acknowledged sub-optimal glycaemic control) was to help individuals find a way to relate differently to their condition. In some senses the model of relating to difficulty that mindfulness presents is a model for the way in which they could learn to live with diabetes and its attendant difficulties. For example practices of turning towards rather than away from difficulty might help to counteract avoidant coping mechanisms in PLWD. Learning

to take wise action rather than react habitually might help PLWD to continue with self-care behaviours even when stressed, or distressed. Developing an attitude of compassion towards ones self might be an antidote for perfectionistic thinking and emerging core beliefs about not being “good enough”.

The protocol used differed from the standard MBCT model in a number of important ways (see Appendix 1 for protocol for 8 week intervention):

- There was no stipulation to do any formal practice other than a suggestion to do ‘something mindfully’ every day. This mindfulness intervention was derived from the experience of piloting the standard eight-week MBSR programme with people who had diabetes and difficulties establishing adequate glycaemic control. We had found that they responded very negatively to the discipline of a formal meditation practice (although they were very interested in the use and potential benefits of meditation itself). They engaged in all-or-nothing thinking about the mindfulness practice itself. This seemed to activate the very same perfectionistic thinking which we were trying to use meditation to help them overcome. In essence mindfulness practice became perceived as another ‘task’ that they were required to do in order to manage their diabetes better. As a consequence of this they disengaged with the home mindfulness practices and dropped out of mindfulness treatment. Dialectical Behavioural Therapy (DBT) often relies on informal practices such as mindfulness of everyday activities as it is recognised that the Borderline Personality Disorder (BPD) clients for whom it is formulated find it hard to engage in lengthy formal practices, Linehan (1993). It was therefore decided to adopt this emphasis and to try to

encourage participants to integrate mindfulness into their everyday life from the first session onwards.

- A loving kindness meditation (based on practices used by the Spiritual Care programme of the Rigpa Fellowship, of which Sogyal Rinpoche is spiritual director) was included in the programme to facilitate the development of kindness towards the self and self-compassion.
- There was little emphasis on teaching ‘thought catching’ and other cognitive therapy skills as these were felt to be less clearly relevant to PLWD.

Evaluating New Interventions

Complex interventions, for example group or individual psychotherapies or behavioural change strategies, involve many interdependent factors (Campbell et al, 2000). Campbell et al (2000) point out that it is more straightforward to evaluate the effects of a single intervention such as a drug than a complex intervention. RCTs are costly and time consuming so they can usually only be justified once a treatment has been shown to be beneficial (Barker, Pistrang & Elliot, 2002). Campbell et al (2000) propose that the development of a new intervention and the process of evaluating it up to the level of an RCT could be conceptualised as phases through which researchers and clinicians might progress in a linear or iterative manner. They describe a preclinical/theoretical stage and four phases (modelling, exploratory trial, definitive randomised controlled trial and long term implementation):

- a) Preclinical or theoretical phase – Researching evidence that the intervention may have the hoped for outcome. Has the intervention been shown to be effective in a closely related condition, or the same

condition in another healthcare system? Hypothesising about the active ingredients of the intervention and revising hypotheses based on new theories and experiential evidence.

- b) Phase 1 – Modelling – understanding the components of the intervention and their interrelationships. This might be done through descriptive studies, qualitative techniques such as focus groups, surveys or case studies
- c) Phase 2 – Exploratory Trial – the information from phase 1 is used to develop the optimum intervention and study design. To allow sample sizes to be calculate this should be randomised so that the effect size can be assessed. Potential outcome measures should be piloted. The intervention or alternative care to be offered to the control group should be decided. This phase can also determine the acceptability to patients and feasibility of delivering the intervention in the healthcare setting.
- d) Phase 3 – Randomised Controlled Trial
- e) Phase 4 – Long Term Implementation – determining whether the intervention can be replicated reliably to give good results in uncontrolled settings over the long term.

This study will be exploratory in nature addressing issues pertaining to the preclinical and modelling phase of complex intervention evaluation in the Campbell et al (2000) model of developing research to the level of an RCT. Campbell et al (2000) stress the importance of combining qualitative and quantitative research methodologies particularly in these phases.

Mixed Methodology

The pragmatist research paradigm (Howe, 1988) asserts that quantitative and qualitative paradigms are neither exclusive nor interchangeable. Barker, Pistrang and Elliot (2002) point out that all research methods have limitations and this makes the approach of triangulation (measuring the same variable with multiple methods) important. In addition, some research approaches are more appropriate to particular research questions than others. For instance when exploring a previously unresearched area qualitative methods are very suitable as they can provide rich descriptive information. Indeed, McLeod (2001) makes the point that qualitative descriptions of how change occurred in a psychotherapy outcome study add to any quantitative data demonstrating the change. Macran, Ross, Hardy and Shapiro (1999) go further stating “We cannot fully know about clients’ experiences, and therefore fully understand how psychotherapy facilitates change, without asking them”. For these reasons this study will use both qualitative and quantitative methodologies.

Research Questions

This study will evaluate the acceptability and feasibility of running an MBCT programme adapted specifically for individuals living with diabetes. The intervention will be piloted with individuals as well as being offered to a group of self-referring outpatients with diabetes.

Overall questions for the study include:

- a) Is a modified MBCT programme acceptable to people with diabetes and do they find it helpful?
- b) Is the intervention feasible in this clinical setting?
- c) Are there were any difficulties with the intervention or drawbacks to using it?

Quantitative Study

Systematic Case Studies

A power calculation based on Cohen (1992) for a pre- post- design with a medium effect size (based on the Grossman et al, 2004 review) revealed that approximately 107 participants would be needed in order to detect a significant effect (using non-parametric statistics) for this kind of study. It was felt that it might be a waste of the participants time if it could be demonstrated after a single group that people with diabetes do not find this an acceptable or useful intervention. It was therefore decided that a small N design would be most appropriate for this exploratory study.

The study's design will treat the individuals as a case series. Barker, Pistrang and Elliot (2002) summarise the features which could be used to improve the quality of single case studies by:

- Use of systematic quantitative data
- Multiple data collection points over time
- Using multiple cases
- Demonstrating change in previously chronic or stable problems
- Demonstrating immediate or marked effects following the intervention

The study was designed to try to incorporate all of these points to enhance internal validity. Pre, post and weekly quantitative measures were administered to track change over time and demonstrate whether or not change occurred following the intervention. The participants self-referred from a population of people with diabetes who experience stress and emotional distress related to their diabetes self-management and had done for many years and they will form a series of case studies who have received the same protocolised intervention.

Elliot (2002) recommends taking an interpretive approach to evaluating change and its causes in single case studies of the outcome of therapy. In order to do this the following points are important:

- To demonstrate that change has occurred
- To examine evidence for concluding that the intervention brought about the change
- To examine alternative explanations for change

- To examine which processes in the therapy might have been responsible for change

Elliot also recommends collecting a “rich case record” of information on therapy outcome and processes, for instance information from different perspectives (e.g. clients and therapists) and different types of data (quantitative and qualitative). This study will combine qualitative and quantitative approaches. Qualitative interviews will be used to explore the participant’s ideas about how any changes were brought about (these might include therapeutic techniques, process or other factors). Measures of mindfulness (pre and post) and self-compassion (pre, just before introducing compassion enhancing techniques and post) will be used to show that the intervention does enhance mindfulness and compassion. Both the quantitative measures and qualitative interviews will be used to demonstrate what changes have occurred.

Quantitative Research Questions

Self-report measures will be used to provide pre and post intervention measures of outcomes. This will provide preliminary data on whether the intervention is associated with any changes in diabetes related emotional distress, self-management behaviours, low mood and anxiety. Quantitative methodology will be used to:

- a) Allow potentially relevant self-report measures to be piloted to find out whether:
 - i) they are acceptable to the participants and whether they are feasible to administer
 - ii) if the measures capture any important changes which the participants describe in the qualitative interviews

iii) if they provide outcome and mediating factor information which could be used to answer future research questions.

b) Is participation in an MBCT programme associated with improvements in psychosocial outcomes relevant to diabetes (diabetes related emotional distress, self-management behaviours, low mood, anxiety)?

c) Is participation in MBCT associated with improvements in diabetes self-management as measured by self-report measures?

Qualitative Study

Qualitative research requires a separate framework of evaluation to quantitative research. Elliot, Fischer & Rennie (1999) have proposed some guidelines for reviewers of qualitative research. They suggest that good quality qualitative research do the following:

- The authors should describe their own theoretical orientation and biases to allow the reader to evaluate their interpretation of the data. This will be included in the methods section.
- The participants should be described so that the reader can decide how widely applicable the findings might be. This will be included in the methods section.
- If a general understanding of a phenomenon is sought then an appropriate range of participants and contexts should have been sampled to achieve this (see methods and results)
- The researchers should aim to stay close to their data and clearly label any interpretations which go beyond the data. (see results)

- They should also provide enough examples of the raw data to allow the reader to understand the analytic process. (See results and appendix 7)
- The author's interpretation of the data should be coherent and integrated but not oversimplify the data. (see results and discussion)
- The researchers should provide means of checking the credibility of their findings for example auditing the analysis (where several researchers check the results against the data), checking the findings with the original participants (provides testimonial validity) and triangulation (exploring the phenomena from different perspectives). (see methods)
- Finally, the results should be believable to the reader and help them to make sense of the phenomenon. (see results and discussion)

These principles will guide the qualitative arm of the study.

In line with the recommendations regarding the development and evaluation of complex interventions a qualitative arm of the study was also carried out. This was to allow the researcher to gain a sense of the participants' individual experiences of taking part in the intervention. This is important in order to check no ill effects were occurring during the intervention. As the intervention had never been offered before there was little previous research to base ideas about what the outcomes of the programme might be. The qualitative information about the benefits and behavioural

changes noted would also provide triangulation for the speculative quantitative self-report measures.

Qualitative Research Questions

Qualitative methodology will be used following the intervention to enquire about participants' views of the experience of taking part in a mindfulness intervention in a diabetes care setting. The researcher hopes that the use of qualitative interviews will enable them to ask 'how' questions of the participants (how do they think the intervention was able to help them?). In particular:

- What were the perceived benefits and costs of taking part in the intervention?
- Whether these benefits and costs were specific to the use of mindfulness or the general experience of taking part in a group intervention?
- Whether intervention helped them make positive changes to Diabetes self-management - i.e. to make behavioural change?
- Whether the intervention helped them to relate differently to the condition or changed their response to the demands of the condition?

Summary of Research Aims

In summary, the study will enable the investigators to pilot a complex mindfulness-based intervention specifically adapted for PLWD. The study will use mixed methodologies to investigate the research questions (defined above) and to establish the feasibility of the proposed investigative methods to examine these questions. The study has been conceived to provide descriptive information about the benefits and any negative effects associated with this new mindfulness for diabetes programme. It

will pilot the procedures and design in preparation for a future feasibility trial if the intervention is shown to be beneficial and acceptable to people with diabetes.

Method

Design

The study utilised mixed methodology to evaluate a new mindfulness intervention for PLWD. The quantitative arm of the study consisted of a case series with pre and post intervention and weekly measures. In addition the qualitative branch of the study asked the participants for feedback using qualitative interviewing post intervention.

The Setting

The Diabetes Service at the Royal Free Hospital (RFH) offers an outpatient and inpatient liaison service. It consists of Consultant Endocrinologists, Clinical Nurse Specialists, a specialist Dietician and a Clinical Psychologist. At the start of the evaluation this treatment did not exist and there were no other group psychological interventions for people with diabetes being offered in the treatment setting.

As the psychology service was very small the Clinical Psychologist was keen to investigate time efficient interventions such as groups. Patients coming to the psychology service are encouraged to express preferences about their treatment. In the spirit of this, the wishes of potential participants opting for individual rather than group treatment were respected. It was therefore decided to offer the intervention on an individual and group basis and to collect the same data from all participants.

Participants

Subject numbers

The researcher aimed to recruit 15 people for an initial pilot group intervention. This was to allow for some participants to drop out and still leave a case series with rich quantitative and qualitative data in order to address the research questions.

Target population

People living with diabetes (either Type 1 or 2) who would be entitled to tertiary care at the Royal Free Hospital (RFH).

Exclusion criteria

- i) Being under the age of 18 years or having a learning difficulty. There are few published studies of MBSR programmes in children or young people or people with learning difficulties.
- ii) People at risk of developing psychosis or currently experiencing psychotic phenomena. This will be especially important as the prevalence of psychosis is higher in people with diabetes than in the general population (Mukherjee et al, 1996). Reports in the literature implicate meditation as a precipitating factor for psychosis (Chan-ob & Boonyanaruthee, 1999; Sethi & Bhargava, 2003; Walsh & Roche, 1979).
- iii) People currently experiencing Post-Traumatic Stress Disorder (PTSD) especially flashbacks of traumatic events. There are few studies using mindfulness-based approaches with people following trauma, it is therefore not know whether

mindfulness practices could exacerbate symptoms. In addition Walsh & Roche (1979) report surfacing of repressed memories and conflicts during meditation.

iv) Being unwilling to commit to the programme (i.e. eight, two hour sessions and follow-up meetings and home mindfulness practice to participants' own ability).

Recruitment

The investigators publicised the group by placing posters and flyers in the waiting room at the RFH and by giving talks to patient groups. Members of the endocrinology team at the RFH also made patients aware of the programme in their consultations with them. Anyone interested in the intervention was invited to refer themselves by completing a reply slip.

Screening

The author responded to all reply slips by telephone to invite interested people to meet with her. Between the conversation and first meeting the respondents were sent the patient information sheet (see Appendix 2) and were asked to fill in a pack of screening questionnaires. The screening pack included:

- a) A demographic questionnaire (to collect information on educational level, gender, marital status, current occupation and income, ethnicity)
- b) A question about previous experiences with mindfulness (e.g. meditation, tai chi, yoga)
- c) The Primary Care Evaluation of Mental Disorders Patient Health Questionnaire PRIME-MD PHQ (Spitzer, Kroenke & Williams, 1999) to alert the investigator to symptoms of anxiety, depression, eating disorders, somatoform disorders, alcohol misuse and usage of medication for mental

health problems. The PRIME-MD PHQ is a self-report version of the PRIME-MD (Spitzer, Williams & Kroenke, 1994) an instrument for use by primary care clinicians that diagnoses specific disorders using diagnostic criteria from the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) (American Psychiatric Association, 1994). Spitzer et al (1999) showed that there was good agreement between PRIME-MD PHQ diagnoses and those of independent mental health professionals ($\kappa = 0.65$; overall accuracy 85%; sensitivity 75%; specificity 90%).

The potential participants met with the researcher in person to hear about the intervention and ask any questions they had. The researcher also conducted a clinical interview to check for any of the exclusion criteria being met. During this process three interested people had to be excluded from the study and were offered referrals to local services because they met the exclusion criteria. One was 15 years old and experiencing psychotic phenomena, one was currently hearing voices and one was suffering from PTSD and actively experiencing flashbacks and dissociation.

Consent

During the course of the screening meeting the remaining interested parties (who had not met the exclusion criteria) completed the consent forms with the researcher (see Appendix 2).

Description of Intervention Completers

Eleven people started the group intervention. Four people, who were not available at the time the group was to be run, were offered the intervention on an individual basis.

Table 2 provides the main demographic and medical information provided by the participants who completed the intervention. Those who completed the intervention were participants who had attended 4 or more sessions of the group. People who completed fewer than 8 sessions were only considered completers if they felt they had completed the intervention by the end of the group intervention. Based on these criteria, 7 group members and two individuals completed the intervention.

The Facilitators

The group was facilitated by the author and a Clinical and Health Psychologist. The author also facilitated the individual intervention. It consisted of the same 8-week programme as described for the group but each session lasted for one hour. The mindfulness exercises were the same and lasted the same duration as for the group. Group enquiries and discussions were conducted on an individual basis and group activities were omitted.

I have been a Buddhist meditator for eleven years. I have been training as a meditation instructor (at a Buddhist centre offering meditation for the general public) for three years. I have been training as a Spiritual Care facilitator (training carers, professionals and people living with illness to use meditation and compassion practices) for four years. I also took part in staff MBCT training at South London and

Maudsley NHS Trust and helped with research into the benefits of mindfulness for mental health professionals there. The other facilitator has had a meditation practice for two years and has completed MBCT training through the Bangor centre for mindfulness practice and research. He is very experienced in running CBT groups for people with physical and mental health problems including diabetes.

Table 2 Demographic and Medical Information for Intervention Completers

Participant (G = group I = Individual)	Gender	Age	Type of Diabetes	Occupation	Weeks Attended the Intervention	Previous Experience of Using Meditation, Tai Chi or Yoga
G1	Female	57	Type 2	Employed	Weeks 2 to 8	None
G2	Female	64	Type 2	Retired	Weeks 2 to 4 & 7	Yes
G3	Male	64	Type 2	Unemployed due to disability	Weeks 1 to 6 & 8	Yes
G5	Female	30	Type 1	Employed	Weeks 1, 3, 4, 8	Yes
G8	Male	40	Type 1	Employed	Weeks 1, 2, 4, 6 to 8	None
G10	Female	54	Type 2	Employed	All 8 weeks	None
G11	Female	38	Type 1	Employed	Weeks 2 to 8	None
I1	Female	41	Type 1	Employed	All 8 weeks	Yes
I2	Female	38	Type 1	Self-employed	Weeks 1-6, 8	Yes

Description of Intervention Non-Completers

Table 3: Demographic and Medical Information for Intervention Non-Completers

Participant (G = group I = Individual)	Gender	Age	Type of Diabetes	Occupation	Weeks Attended the Intervention	Stated Reason for Leaving the Intervention	Previous Experience of Using Meditation, Tai Chi or Yoga
G4	male	70	Type 2	Retired	2	Unable to hear well enough to participate in group discussions	None
G6	female	58	Type 1	home maker	1	"it's not for me"	None
G7	Male	62	Type 2	Unemployed due to disability	5	Decided to return to a psychotherapeutic group running at the same time as the intervention	Experience of meditation
G9	Female	19	Type 1	Student	3	Illness	none
I3	Male	41	Type 2	employed	1	None given	None
I4	female	52	Type 1	employed	1	Pressure of work unable to attend sessions during office hours	Experience of meditation

Procedure

The intervention ran for 8 consecutive weeks each group session lasted for 2 hours. The pre and post measures were completed by the participants at the start of sessions 1 and 8. In addition, the self-compassion scale was also administered at the start of session 5 during which the loving kindness practice was introduced. It was hypothesised that the mindfulness-based intervention alone would alter the participants' compassionate attitudes towards the self so it was deemed necessary to include a second baseline for this measure in order to gain an impression of the effect of adding the compassion practice. The WHO-5 was completed at the start of each session and the HAT was completed at the end of each session.

The group participants were invited to attend a focus group to share their experiences of the programme the week after the completion of the intervention. In order to create a context where the participants could feel free to talk about any difficulties with the intervention, including the facilitation, an independent Clinical Health Psychologist moderated the focus group. For the same reason the other group facilitator who had not previously met the two individual participants, interviewed them the week after they had completed the intervention. The same semi-structured interview schedule was used for the individual and group interviews.

The focus group members were invited to a session to comment on the themes derived from the transcript of the focus group. This was to provide a testimonial validity check of the data.

Measures

(See Appendix 4 for measures)

Pre & Post Measures

The following measures were completed at the first and last weeks of the intervention and at the start of the session to avoid contamination by any possible mood altering effects of practising mindfulness:

1) Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983)

The HADS was used to indicate levels of anxiety and low mood symptoms in the participants. The HADS is a useful measure because it does not include items about somatic symptoms of anxiety and depression thus preventing overlap between chronic illnesses and indicators of anxiety and depression. The HADS contains 14 items and consists of two subscales anxiety (HADS-A) and depression (HADS-D). Each item is rated on a four-point scale (0-3), giving maximum scores of 21 for each sub-scale. Mean Cronbach's alpha coefficient of internal consistency for the HADS-A was found to be 0.83 and 0.67 for HADS-D by Bjelland et al (2002). Nunnally & Bernstein (1994) recommend that a Cronbach's coefficient alpha should be at least 0.60 for a self-report measure to be reliable. Evaluating the HADS as a case finder for anxiety disorders and depression, Bjelland et al (2002) found that an optimal balance between sensitivity and specificity was achieved most frequently with a cut off score of 8+ for both the HADS-A and HADS-D. This gave sensitivities and specificities for both subscales of approximately 0.80.

2) Problem Areas in Diabetes (PAID) Scale

Diabetes related emotional distress was measured using the PAID. The PAID is a measure of negative emotions towards diabetes and its treatment (e.g. feelings of guilt, anger, frustration, depression, worries, fear of complications and future). There are 20 items scored from 0 to 4, with scores added to give a total out of 100. Higher scores on the PAID represent higher levels of diabetes related emotional distress. Internal reliability for the PAID is high Cronbach's $\alpha = 0.95$ and tests of concurrent validity indicated that it was significantly associated with relevant psychosocial measures of distress (including general emotional distress, disordered eating and fear of hypoglycaemia), (Polonsky et al, 1995).

3) Summary of Self-Care Diabetes Activities (Toobert, Hampson & Glasgow, 2000)

Included to assess frequency of self-management behaviours. Respondents are asked to indicate how often they perform diet, exercise, blood glucose monitoring, foot care and smoking behaviours over the past seven days with at least two items per behaviour. The mean number of days the recommended behaviours were performed for each category will be calculated. Internal consistency of the subscales has been reported as acceptable (mean inter-item correlations 0.47) with the exception of the dietary subscale, which was less reliable ($r = 0.07-0.23$). Test-retest correlations have been shown to be significant (mean $r = 0.40$), (Toobert et al, 2000).

1) Mindful Attention and Awareness Scale (MAAS) - Brown & Ryan (2003)

The MAAS was included as a validity scale to check whether mindfulness (one of the constructs the researchers were hoping to manipulate) altered during the intervention. The MAAS has 15 items and respondents indicate on a 6-point likert

scale how frequently they have the experience described in the items. The scores are summed and higher scores indicate higher levels of mindful awareness and attention. Internal consistency was found to be high (Cronbach's $\alpha=0.87$). The MAAS was also shown to have validity in a general adult population, to be tapping a distinct psychological construct and to discriminate between groups of people expected to differ in degree of mindfulness (Brown & Ryan, 2003).

2) Self-Compassion Scale (SCS) Neff (2003)

As the MAAS was not designed to tap acceptance or self-compassion the SCS was additionally included as a validity measure (one of the constructs the researchers were hoping to manipulate was self-compassion). The SCS is a 26 item scale which has 6 factors: self-kindness, self-judgement, common humanity, isolation, mindfulness, over-identified (with distress) scores from these dimensions are summed to yield a total self-compassion score. The internal consistency for total SCS was 0.92. Construct validity for the scale was found to be good. The SCS was found to significantly predict mental health correlating negatively with the Beck Depression Inventory and Speilberger Trait Anxiety Scale. It also negatively correlated with a measure of perfectionistic thinking style (Neff, 2003).

WHO-5 Well-Being Index (WHO, 1998)

The WHO-5 was included as a weekly and pre and post measure. It was derived from a larger rating scale developed for a WHO project on quality of life in people with Diabetes (WHO, 1990). It was chosen as a quick measure of well-being. The five items cover positive mood, vitality and general interests. The items are rated on a 6-point scale and the scores for each item are totalled. The maximum score is 25,

scores below 13 indicate Major depression. Henkel et al (2003) showed that the WHO-5 had 93% sensitivity and 64% specificity for identifying depression in primary care patients.

Helpful Aspects of Therapy (HAT) Form (Llewelyn, 1988)

The HAT was included to collect feedback about which parts of the intervention the participants found especially helpful and hindering. It was administered at the end of each session. This measure will provide triangulation for the impressions of the facilitators about which parts of the intervention worked well and what could be improved. The HAT is a brief, open-ended questionnaire, which will be completed by the participants after each session. Clients are asked to describe in their own words the most helpful event in the session, and to rate how helpful it was. They are also asked about other helpful or hindering events in the session. Llewelyn (1988) analysed the HAT using a form of content analysis to obtain the frequencies that different pre-determined aspects of therapy were reported as being helpful or hindering by the clients. It was decided to adapt this method and to derive the categories thematically from the data rather than applying pre-conceived categories to it. Having derived categories of helpful and hindering aspects the frequency with which they were endorsed as being helpful or unhelpful was recorded. Since some exercises were practised more than once the total number of possible endorsements varies.

Case Series Analysis

The mean scores for all the participants will be compared to look for any evidence of change. The SCS will be compared pre and immediately before the introduction of

the loving kindness practice and then pre loving kindness and post intervention to try to ascertain the affect of adding the self-compassion component. The WHO-5 weekly means will be examined to look for a trend in any changes. The HAT questionnaires will be analysed using content analysis (see above for description).

Qualitative methods

Focus Group

Focus group methodology was employed to collect participants' views about the experience of the mindfulness intervention with minimum contamination from the beliefs and attitudes of the interviewer. This is particularly important in the evaluation of a new intervention where such issues may influence responses due to social desirability and the impact of power imbalance between researcher and participant, which may be amplified in a clinical research in which the researcher is also the clinician. Furthermore, Wilkinson (2003) points out that focus groups are a more 'naturalistic' context than one to one interviews and as such participants use everyday language and a range of communication processes such as joking, empathising, disagreeing, challenging and debating issues. Hence, focus groups are useful in health research because the interactive quality of group communication results in greater disclosure, more elaborated accounts, better understanding of each individual's agenda and an opportunity to observe the co-construction of meaning (Wilkinson, 1998). In addition, it was hoped that the group participants would be comfortable with discussing their experiences as a group having taken part in the intervention together. Use of a focus group was also favoured because it was a time efficient way to interview the participants.

Four participants took part in the focus group (G1, G3, G8, G10). Two members of the focus group (G1, G10) attended the testimonial validity check and both agreed with all the themes presented to them. They expanded further on their earlier discussion and clarified some points from the focus group. This conversation was transcribed and added to the analysis.

Two participants (G2 & G5) were on holiday at the time of the focus group but were keen to contribute and were interviewed individually by the author. An interview with the remaining member of the group has been arranged for after her university exams. The two individual intervention participants (I1 & I2) were interviewed individually.

The focus group lasted for two hours and the individual interviews for an hour in both contexts some time at the start and end was devoted to practising mindfulness with the facilitator.

Semi-structured interview

A semi-structured interview schedule was used to collect information from both the focus group and individual interviewees. Questions were designed to elicit a narrative of the participants' experiences of using mindfulness (positive and negative), how any changes had come about and mindfulness had related to their experience of living with diabetes. (see Appendix 5 for examples of the questions used).

Analysis of Qualitative Data

The focus group and individual interviews were audio-taped and transcribed (see Appendix 6 for transcription conventions used). The researcher listened to the tapes and checked the transcriptions for accuracy. The data was then analysed thematically. It has been proposed that thematic analysis is more holistic than other forms of qualitative analysis because it can capture a substantial proportion of the data and it allows the same data to be analysed in several ways (Peel, Parry, Douglas & Lawton, 2004). Themes were defined as “a pattern found in the information that at the minimum describes and organises possible observations or at the maximum interprets aspects of the phenomena” (Boyatzis, 1998). The transcripts were then read and annotated for themes summarising the content of the articulations (see Appendix 7 for examples). The themes from all the transcripts were collected into a new document. The transcripts were reread line by line, any utterance illustrating a theme was then cut and pasted beneath the theme title. During this process new themes occurred to the researcher and these were included and the analysis process repeated. In order to present the results these aggregated themes and quotes were reread and quotes which best illustrated the themes were chosen.

Stance of researcher:

The data will be analysed from a contextualist epistemology in which knowledge is defined as “local, provisional and situation dependent”, Jaeger & Rosnow; 1988). Contextualist analysis accepts the inevitability of bringing one’s personal and cultural perspectives to bear on the collection, construction and interpretation of

research data (Madill, Jordan, Shirley, 2000). Consequently as the researcher, I will inevitably make sense of the data and construct an account of the participants' experiences based on my own experiences and theoretical standpoint. It is therefore important (and in accordance with Elliot et al's (1999) guidelines for enhancing the validity of qualitative research) to indicate what these are: I am a Buddhist woman in my early thirties with experience of living with chronic illness (although not diabetes). As a psychologist my practice is informed by the scientist practitioner model but tends to be integrative (when I am not working in a mindfulness based way) and aspires to be evidence based. I hope to read the transcripts from a feminist experiential position (Wilkinson, 2000) valuing the unique experience of individuals, regarding them as 'experts' on their lives and their own experience. I will attempt to listen to participants' articulations of their own meanings and base my analysis on their articulations rather than applying existing analytic frameworks. Wilkinson (2000) suggests that this allows participant's experiences to be understood and represented in their own terms and may also allow fresh insights to emerge. This will be helpful in exploring the range of participants' experiences especially because mindfulness for PLWD is an unknown phenomenon.

Validity Check

Checks on the qualitative data analysis were carried out in two discrete stages. The first of these comprised a check on the reliability and validity of the categorisation of transcript data to broad themes within the material. The second stage comprised a validity check on the synthesis of material from these themes to answer the research questions around which the investigation was constructed. It should be noted that the

interviews and focus group generated much data which was not necessarily related to the research questions.

1. Validity of the broad themes generated from decomposition and interpretation of focus group and interview data.

This was carried out in the following stages:

- a. Reader 2 (R2) read through a randomly identified selection of 2 individual and the focus group transcripts and identified their own themes in response to the material. This was carried out without knowledge of the categorisation of Reader 1 (R1).
- b. R2 was given R1's categorisation of the same material and identified any significant differences, differences or omissions in the material and its categorisation, which will be discussed in the discussion section.
- c. R2 and R1 met to discuss the identified differences and agreement was reached about how best to classify the material.

2. Validity of the analysis

Once broad agreement of the conceptual categories within the transcript was achieved the second stage in the validity check was to assess the synthesis of this material to answer the four research questions.

The stages of this were as follows:

- a. R1 constructed the analysis and presented it to R2.
- b. R2 read the analysis and identified areas where the analysis did not fit with their own interpretation of the presented data.

- c. Discussion took place about how best to identify material answering the research questions.

The themes will be discussed in terms of how they relate to the original research questions. New understandings and insights that have emerged from the data will be discussed in a separate discussion section.

Ethical Approval

Ethical approval for the study was granted by the ethics committee of the Royal Free Hospital (see Appendix 3).

Quantitative Results

The individual and mean pre and post scores for the HADS and PAID are displayed in Table 4.

Table 4 Showing pre & post anxiety, depression (HADS) and diabetes distress scores (PAID)

Participant	Pre-HADS Anxiety score	Post-HADS Anxiety Score	Pre-HADS Depression score	Post-HADS depression score	Pre-PAID score	Post-PAID score
G1	11	1	8	1	51	45
G2	9	9	3	4	35	47
G3	10	16	16	15	50	43
G5	10	14	7	10	55	48
G8	-	9	-	5	34	19
G10	-	5	-	7	49	30
G11	9	3.5	8	6	38	17
I1	5	7.5	0	5.5	54	26.5
I2	8	10	1	4	27	37
Means	8.9	8.3	6.1	6.4	43.7	34.7

HADS scores indicating clinical caseness in **bold**

HADS Anxiety Scores

Mean HADS anxiety scores for the participants showed little change from start to finish of the intervention. The mean scores for the participants appear to be quite

high starting and finishing above the clinical cutoff score of 8. In an epidemiological study, 40% of the PLWD surveyed showed raised symptoms of anxiety (Grigsby et al, 2002). This may be evidence that this group of individuals are amongst the more distressed part of the population of PLWD.

HADS Depression Scores

Mean HADS depression scores did not appear to change over the course of the intervention and was on average below the clinical cutoff score of 8. Gavard, Lustman & Clouse (1993) estimate that depression affects one in five of PLWD, which is around three times the rate in the general population.

PAID Scores

The mean score for diabetes related emotional distress fell by 9 points. In a Dutch study evaluating group CBT for diabetes the Dutch version of the mean PAID score for their sample of 107 participants at baseline was 42.81 (Van der Ven et al, 2005). This was similar to our samples pre intervention mean PAID score of 43.7.

WHO-5 Wellbeing Scores

Table 5 Weekly Well-Being Scores

Participant	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
G1	-	8	15	13	19	15	16	21
G2	2	11	7	14	-	-	9	10
G3	3	12	8	1	7	4	-	4
G5	9	-	-	-	14	-	-	7
G8	16	16	-	17	-	18	16	17
G10	6	10	13	12	12	12	9	13
G11	-	7	-	14.5	11	15.5	-	17
I1	15	13	13.5	14	14.5	14	15	17.5
I2	18	14	13	18	14	-	-	11
Means	9.9	11.4	11.5	12.9	13.1	13.1	13.0	13.1

Bold = scores below 13 indicative of Major Depression

The mean well-being scores suggest that well-being increased slightly from week 1 to 5 and then plateaued out. The lack of change in wellbeing/low mood indicators is in line with HADS depression scores.

Diabetes Self-Care Behaviours

The mean results for the participants in carrying out their recommended diabetes self-care tasks between the beginning and end of the intervention are shown in Table 6. For the diet domain there was a slight increase in the number of days per week the

participants were following the recommendations from 4 to 4.5. In terms of exercise, the mean number of days per week that the recommendations were being followed fell slightly from 2.3 to 2.1.

With regards to blood sugar monitoring there was a slight increase from 4.1 to 4.3 in the number of days per week when the recommendations were followed. Meanwhile there was no change from start to finish of the intervention for taking all prescribed medications (including insulin).

There was an increase in the mean number of days foot care behaviours were carried out from start to finish of the intervention from 3.2 to 4.5.

The majority of the participants were non-smokers, however the mean number of cigarettes smoked per day fell from 3 to 1.1 from start to end of the intervention.

Table 6 Diabetes self-care scale (mean numbers of days per week recommended behaviours are being performed)

Participant	Diet Pre	Diet Post	Exercise Pre	Exercise Post	Blood Sugar Testing Pre	Blood Sugar Testing Post	Taking Meds Pre	Taking Meds Post	Foot Care Pre	Foot Care Post	Number of Cigarettes/ Day Pre	Number of Cigarettes/ Day Post
G1	3.6	5.4	2	3	0	0	7	7	5	6.2	0	0
G2	4.2	1.8	2	0.5	5	5.5	7	7	3	4.8	0	0
G3	0.6	4.8	0	0	7	7	7	7	2.8	6.2	25	0
G5	4.0	2.0	2	0.5	0.5	1	7	7	4.2	4	0	0
G8	3.3	4.6	1.5	2	3	3.5	7	7	4.2	4.6	0	0
G10	4.8	5.6	1	2	7	6.5	7	7	2	4.8	2	10
G11	4.2	5.8	3	2.5	4	4	6	6	1.6	1.8	0	0
I1	5.6	5.5	5	6	3	4	7	7	2.8	4.2	0	0
I2	5.5	5.2	3.8	2	7	7	7	7	3.2	3.8	0	0
Means	4.0	4.5	2.3	2.1	4.1	4.3	6.9	6.9	3.2	4.5	3	1.1

Validity measures

Table 7 Mindfulness Awareness and Attention Scale (MAAS)

Participant	Pre	Post
G1	61	41
G2	29	31
G3	34	38
G5	35	38
G8	79	89
G10	62	62
G11	50	57.5
I1	53	62.5
I2	73.5	67
Means	52.9	54

Mean mindfulness and awareness scores showed little increase from start to finish of the intervention.

Table 8 Self-Compassion Scale Total Scores

Participant	Pre	Mid	Post
G1	13.45	12.85	17.95
G2	9.25	-	11.50
G3	13.52	10.10	12.50
G5	15.00	-	11.20
G8	20.72	-	28.95
G10	14.35	16.20	17.90
G11	14.67	17.60	18.40
I1	9.60	12.24	16.95
I2	19.45	18.38	19.05
Means	14.4	14.6	17.2

Mean self-compassion scores showed little increase between baseline and mid-point. However, after the introduction of the self-compassion practice they increased from 14.6 to 17.2.

HAT

The most endorsed items (with more than 10 mentions of the HAT forms) were: sitting meditation, hearing about other peoples' experiences and discussing how to integrate the formal practices into everyday life.

Hindering events were: being invalidated by another participant in listening exercise, hearing about other peoples distress, being unable to generate an image of

unconditional love in the loving kindness practice, noise outside the room, being afraid of having your mind controlled so feeling unable to enter into the practices, feeling afraid to discuss own version of meditation practice for fear of being judged by the facilitators.

Table 9 Showing the items endorsed on the HAT as Helpful or hindering

Practice	Number endorsements for number of participants	Mean Helpfulness ratings (ratings from 1 to 9; 1 = extremely hindering, 5 = neutral, 9 = extremely helpful)	Comments? Dissenters?
Hearing others experiences	17	7.8	Preferred being a smaller group, feeling comfortable in the group Hindering - Finding other peoples distress difficult = 4
Sitting meditation	16	7.8	Liked use of bells
Talking about integration of mindfulness into daily life	11	8.3	e.g. working with emotions, using mindfulness at the dentist, how to continue after group ends, practicing in many short sessions, effect on blood sugar & smoking
Talking about own experience of practices	8	7.2	
How to apply self-kindness to own thoughts	6	8.5	Concept of acceptance
poems	5	7.7	Especially: Guest house and autobiography in 5 chapters
Loving Kindness Meditation	5	8.3	Use of phrase, connecting with Christian faith, Hindering - hard to think of an example of receiving unconditional love = 3
Mental posture instructions	5	7.5	Analogy from another group member was very helpful
Diabetes problem solving	5	8.3	"Best week so far"
Mindful listening	4	5.8	Not being listened to hindered = 2
Mindful eating	3	8.2	Especially using strawberries
Walking meditation	3	7.7	
Standing meditation	3	7.7	
Idea of exploring difficult feelings/feel feelings	2	7.5	
Body scan	2	7.5	
Breathing spaces	1	7.5	
Style of facilitation	1	7	Calm, quiet not being judged. Hindering - being afraid of facilitators judging how well I meditate
Shifting to being mode ie not having to act	1		
Commitment/kindness graph	1	8	

Discussion of Quantitative Results

Summary of Main Findings

The main findings were that there was little change on the HADS-A and HADS-D measures of anxiety and depression. The WHO-5 measure showed a small increase of well-being but plateaued after week 5. The PAID measure showed a marked reduction of diabetes distress. On the Diabetes Self-Care Inventory the only domains to show clear indication of change were foot care (increased) and smoking (decreased). The MAAS showed a small increase from start to finish. The SCS showed an increase in self-compassion following the introduction of loving-kindness at week 5 but not before it i.e. with just the mindfulness practices.

Answering the Research Questions:

In answer to the research question about whether PLWD found the intervention helpful it could be commented that there was only a 36% drop out rate from the group. This suggests that the majority of participants found the intervention helpful enough to complete the programme. However, two of the dropouts from the group gave reasons for leaving connected to the intervention (it not being for them or preferring another form of group therapy). Two of the four individual participants dropped out of the intervention, the one who stated a reason did so due to work commitments. It was not possible to interview the participants who dropped out of the intervention about their experiences since their volunteering for the study was predicated on their being able to discontinue at any time without stating a reason. This is an issue common to all studies and makes it impossible to say with more

certainty whether some people dropped out due to negative experiences during meditation practices.

In answer to the second question it has proved feasible to offer this intervention in the clinical setting of the RFH diabetes service. It has been well received by patients and valued by the team. The process of setting up the study at RFH will be discussed in paper 3 of this volume.

In answer to the question about side effects to the intervention none were written down on the HAT forms. However, some hindering factors were recorded in the main these seem to be common to other therapy groups (for example feeling invalidated by other members and worrying about what the facilitators made of them). One comment that was specific to mindfulness came from participant G8 who was finding it difficult to allow himself to enter into mindfulness practices.

Qualitative data concerning the participants' perceptions of the quantitative measures acceptability will be presented and discussed in the qualitative section. The next research question concerning whether the quantitative measures captured important changes described in the qualitative interviews will be discussed after the presentation of the qualitative results.

The self-compassion measure does seem likely to be providing useful mediating factor information. The observation that mean scores on the SCS did not increase until after the introduction of the compassion practice are strongly suggestive that it was this practice that was responsible for the increase. With regards to the MAAS

little change was seen in the mean pre and post scores. One of the drawbacks to using self-report measures it is unclear if behaviour has actually changed (alpha change) or whether a response shift has occurred e.g. participants have re-calibrated the measurement scale (beta change) or whether they have re-conceptualised the behaviour (gamma change), (Michie & Abraham, 2004). It is therefore possible that people's concept of mindfulness and their internal scale has shifted over time rather than not getting more mindful over time. This could be because of the difficulties in describing mindfulness in words, which were described in the introduction, giving participants little idea of the concept at the start of the first session. As they discovered what the concept means experientially they ended up in a better position to judge how mindful they are at the end rather than the beginning.

The mindfulness intervention was associated with improvements in self-care and well being and a reduction of diabetes distress. The fact that the intervention had little impact on low mood and general feelings of anxiety (as opposed to diabetes related anxiety) may well reflect the formulation for the intervention which was designed to relieve diabetes emotional distress and support the participants in their self-management efforts. Many of the participants had already received psychological treatments for depression or were taking antidepressants during the intervention. Their experience was that nothing had previously helped them for example G2 said, "None of the previous counselling I've had has ever done me any good".

Qualitative Data

The purpose of the analysis was to describe and analyse the range of experiences reported by participants having taken part in this intervention and the effect this had on their views of their diabetes. For the purposes of this paper themes that relate to our research questions have been focussed on. These were:

- 1) Was the intervention beneficial?
- 2) What were the benefits?
- 3) How did the benefits come about?
- 4) Were there any negatives to taking part?

In addition, themes emerged about the participants' pre-intervention ways of being with diabetes, their relationship with diabetes, their relationship to help and to other people, which will not be considered here. This decision will be discussed in the critical appraisal paper and it is intended to write this data up for publication separately to the results of this empirical paper.

1) Was the Intervention Beneficial?

All eight of the interviewed participants felt that the intervention had been beneficial. For example, G1 "yes, I have benefited, I have benefited" (FG, T42, G1, L44).

However, one participant made it clear that it was not the mindfulness that had benefited him, "I can't say I have benefited from it [mindfulness] but I can sympathise with what

Paul and Sonya are trying to do” (FG, T70, G8, L14). It seemed that practising mindfulness was in conflict with his avoidant coping strategy “Just going into my little trance for like a couple of minutes we’re doing it, it just reminds me that the things that I tried to forget are still there.” (FG, T28, G8, L27). What had proved beneficial for him was being part of a group and coming off well in social comparisons with other members, “it’s probably a rotten thing to say but they always say that when you’re with a group a’ people and you share problems, you come away thinking gee how lucky I am. I’m not as bad as...”(FG, T66, G8, L10).

2) What Were the Benefits of the Intervention?

The participants gave a wealth of examples of the benefits of the intervention. As one of the main research questions was to find out about the benefits of mindfulness were for PLWD all the benefits described by the participants are listed in Table 10. The benefits fall into some broad categories: diabetes specific benefits, coping with emotions, being calming, developing self-compassion, having an awareness of problematic coping strategies and preventing insomnia.

In contrast with the theme about diabetes specific benefits of the programme G1 and G10 both felt that the mindfulness had wider effects than just helping with their diabetes:

“But I don’t know if it’s just the diabetes. I think it’s helping me in other areas.”(FG, T44, G1, L1)

G1 made the point that mindfulness is a form of preventative healthcare:

“What’s good about this is you don’t have to be unwell to benefit from this, you don’t need to wait to be ill.”(VC, T21, G1, L1)

Table 10 Listing the benefits of the mindfulness for diabetes intervention

Theme	Endorsed by:
Calming: “Calming” “Soothing” “Relaxing” Gives time/space (for you)	I1, G3, G2, G5 I2 G3, G2 I1, G1
Helps you Cope with emotions: Helped her to explore/be with her feelings Allows you to have a choice in how you feel about things Makes you less afraid <i>Anxiety:</i> No panic attacks since on course Anxiety connected with being a perfectionist Anxiety about living with diabetes Accepting having worries or not worrying, distracts you from worries <i>Anger:</i> Allowed her not to react in anger to other people Become “less feisty” Given her a choice about whether to stay angry	I1 I2 G10 G3 I1 I2 G1 G3 G1, G2 G3 I2
Diabetes Specific Benefits: “My diabetic problems have been better” Had lower blood sugars or lower HbA _{1c} Checking her blood sugars more frequently Helping him cope with diabetic pain and using less pain medication “I’m eating more sensibly” Enabled her to identify her feelings about diabetes Allowed her to relate differently to diabetes Feeling less guilty when go “off-track” with diabetes self-care tasks Helped her cope with having medical tests and procedures	G3 G3, G1, G10, G5 G10 G3 G3 I1 G5 G1 G1, I2
Developed Self-Compassion: “being a best friend to myself”	I1
Developing an Awareness of Your Problematic Coping Strategies	I2, G5
The Practice Tapes or mindfulness techniques Helped with Insomnia and getting off to Sleep	G3, G5

3) How Did the Benefits Come About?

Themes derived from the ideas the participants expressed included: reversing avoidant coping strategies, helping them overcome anxiety, leading to acceptance of how things are, developing self-compassion, feeling less guilt, being able to respond mindfully rather than react habitually when angry, developing greater awareness, feeling whole, viewing mindfulness as a skill to help them manage their diabetes and helping them cope with pain. The group process rather than, or in addition to, the mindfulness and compassion was also seems to have been an important mechanism for change.

The participants of this study described how they try to avoid thinking about or dealing with their diabetes. For example I1:

“It feels sometimes like my diabetes is kind of locked away, you know. And it takes a lot of energy to keep it locked away like that.” (I1, T46, L5)

Also a similar theme about how avoiding dealing with diabetes takes a lot of energy from G10:

“I mean it was extraordinary to see how similar we are and to find out how much, all the techniques that we use to avoid thinking about diabetes or you know, to sort of you know, pretend you don’t have it or just be so enraged about it, you know. All the hard work that you put into not dealing with diabetes or not dealing with the condition. And the energy that we waste.” (FG, T34, G10, L3)

I2 talks about the function of keeping diabetes at bay (to avoid painful feelings):

“I’ve sort of tried to keep it [diabetes] at bay and I think anything that makes me then think about it on a different level brings up some of that initial pain again, that probably was never resolved at the time and I know is there.” (I2, T40, L8)

The interviewees also described how mindfulness had resulted in their turning towards and experiencing their emotions and body sensations ie reversing their avoidance. They talked about facing up to their diabetes self-care by using the mindfulness techniques they had learnt. I1 described how meditating allowed her to feel her feelings rather than pushing them away:

“It was like the meditating sort of gave me time to, um... to you know, feel the things I was feeling because I think what I normally just do in my day to day life is I kind of just... I don’t feel good so I just push it away.” (I1,T10,L12)

I1 also talked about using the body scan to examine uncomfortable sensations in her body rather than ignoring them:

“when we were doing the body scan stuff... there were times when I couldn’t identify how I was feeling but I was feeling something quite strongly. And it was just trying to, just to look at it to stave off my stomach cramps... I mean I feel most things in my stomach so it’s like if my stomach feels really, you know, whatever it felt that day. And just even that little bit, if I couldn’t figure out what it was, it was OK. Just the fact that I tried to look at it was a really big help.”(I1,T10,L23)

G10 described how taking part in the intervention had led to a shift in her attitude to managing her diabetes enabling her to test her blood rather than avoiding doing it:

“I think what I’ve been doing is I think, well, oh well I’ll just take the bloody blood sugar level and find out. And I have been doing that much more often. And while sometimes you do get high blood sugar levels, now I know that it’s high then I can bring

it down again, rather than thinking, well I wonder what it is. I suspect... I suppose it's like facing up to bad news in a way." (FG, T116, G10, L7)

Coping with Painful Medical Procedures

I2 described using mindfulness of the breath to help her through painful tests. G1 was amazed to find that by focussing on her breath she could have a dental procedure under local anaesthesia that she would have needed a general anaesthetic for before:

"it helped me through a terrible tooth extraction with bone coming away and stitches and all the rest of it, and being able to cope thinking, oh God I'm diabetic, it's never going to heal. And thinking no! Think positive, breathe, concentrate, and everything." (FG, T120, G1, L3)

Working with Anger

Having taken part in the intervention G1, G2, G3 and I2 all talked about being able to respond when angry rather than react habitually. This seems to relate to the mindfulness principle of using 'wise mind' to respond mindfully rather than reacting habitually in difficult situations. For example G1 was able to respond mindfully to her son and not react ("scream, rant, rave, shout"):

"Yes, for example if my son comes home and says, I'm going to Manchester next week, Leeds the week after, Liverpool the week after and I need £200 for all this, I would have gone berserk. Why didn't you tell me? I've got to budget... And I didn't. I just said OK, write it all down and I'll think about it. To me it was amazing. And I mindfully thought about it. I looked at it as opposed to going off the deep end" (FG, T48, G1, L1)

I2 describes how mindfulness has enabled her to have a choice about whether to go along with her anger:

“it’s just thinking to myself that I have a choice, rather than just feeling irritable and letting it overwhelm me and just going with it” (I2, T8, L5)

G2 also mentions that mindfulness has helped her to respond rather than react to other people and also mentions a moment of pause that enables her to do this:

“Mindfulness has helped me be less reactive with other people and be more diplomatic. But I’m very honest with people I can’t pussyfoot around them. It’s good to stop before I say it, that little second, and to say something more kind to the other person.” (G2, T48, L1)

Overcoming Anxiety

Mindfulness was also found to be helpful in coping with other emotions such as anxiety. I1 explained how being mindful of her breath helped her overcome anxiety:

“I often do it sort of around the middle of the day because I think what happens to me is like I wake up in the morning and I sort of start working straight away, and then by the middle of the day, I go (panting) and it’s really you know anxious, panicky. And so I try to do the meditation then because it breaks the cycle, you know. I think just the kind of, you know, breathing... I think the other thing that I’m doing like when I’m very anxious, is that I’m actually not breathing very much or very deeply. And so when I’m focusing on my breathing I do tend to at least slow it down a bit. It feels really calming” (I1, T14, L8)

This extract also describes how the calming effect of mindfulness comes about for I1.

G3 found he could use mindfulness to distract himself from anxious thoughts:

“I think I’ve been more conscious about breathing correctly which in itself is very good because it’s a distraction from the other things which I worry about.” (FG, T132, G3, L2).

Meanwhile, G1 explained how acceptance was helping her to be with her worry:

“I’m not worrying about worrying now or worrying about not worrying for that matter. I’m accepting the worry now, it’s there and that’s ok.” (VC, T4, G1)

Acceptance

In fact, the participants very often credited acceptance with bringing about beneficial effects. In Buddhism (upon which the mindfulness approaches are based) there is a principle of ‘radical acceptance’, which incorporates the belief that everything is perfect as it is. As Kabat-Zinn (1991) explains how this can be applied to chronic health problems “The way of mindfulness is to accept ourselves right now, as we are, symptoms or no symptoms, pain or no pain, fear or no fear.”(pg 280).

At the focus group follow-up meeting G1 and G10 talked about acknowledgement being the first step to acceptance. Segal, Williams and Teasdale (2002) state that accepting something does not mean approving of it or mean that we are admitting defeat. They point out that there is a paradox that if we deal with unpleasant feelings by attempting to control them or push them away we end up maintaining them. I1 talked about friendly acknowledgement of how things actually are as a component to challenging her avoidant coping strategy:

“You know it’s acknowledging that that happens is a little more friendly than saying, no I’m not going to deal with this or, you know, you just pretend it’s not happening. And I mean because I, first of all, just discovering through meditation, now that’s not a very effective policy.” (I1, T12, L3)

G10 described how moving it was for her to be accepting within her mediation practice: “you know, through learning to accept that you can breathe any way you like and there isn’t a right or wrong way, you can be breathing up here or down there or, you know... All of that is OK... that’s such a big thing. To find that things are... it’s OK. And that’s quite... it makes me want to cry. It’s so nice.”

Some of the participants (G8 & G10) talked about the difficulties with “accepting” their diabetes particularly because it seemed to dictate to them and prevent them doing things: “for a long time I didn’t come to terms with the diabetes because like um, I don’t like anything that stops me from doing what I want to do.” (FG, T66, G8, L5)

However, the participants also spoke about a shift in their attitude to diabetes towards acceptance:

“I’ve got to learn to cope with it as it is, not as I want it to be. Diabetes is never going to be as I want it to be.” (FG, T42, G1, L10)

I2 explained that the intervention had led her to be more accepting about the challenge of managing her diabetes:

“it’s more about acceptance than sort of battling, and you know part of me likes that. You know, it’s quite a relief in a way” (I2, T68, L1)

This was one of the hopes of the facilitators that the mindfulness programme would enable the participants to relate to their diabetes differently so that it was not so much of a source of distress to them.

Self-Compassion

As well as acceptance, developing kindness and compassion towards oneself was cited as a mechanism that brought about benefits of taking part in the programme. G10 observed that the intervention was about being kind to yourself in general, instead of being focussed on faulty aspects of you:

“It felt like it was about being a human being, being kind to yourself – that was a big one – not just about the bits of you that didn’t work.” (VC, T5, G10)

I1 described how the programme had resulted in her being more friendly towards herself and that acceptance of her feelings was an aspect of this:

“I feel like I’m being a better friend to myself by, you know... I think that’s probably the way that it’s helped me the most.” (I1, T14, L1) and clarifying the “you know” she added:

“I think it’s been like not sort of kicking myself for not feeling the way I think I ought to be feeling.” (I1, T22, L1)

G3 thought that mindfulness had enabled him to be more self-disciplined and to care for himself: “It somehow or other has disciplined me to take more care of myself” (FG, T54, G3, L43)

Both G10 and I2 talked about how being kinder to themselves helped them overcome the unhelpful aspects of their perfectionistic attitude towards their diabetes self-management:

“I think diabetes is a nightmare for somebody like me who likes to get things done, or get things finished, and do things properly, because it’s so... You can’t get hold of it, ever. And I think the mindfulness is... well I’m beginning to see that it’s a way of taking a more sort of kinder, kind of whole approach to one’s outlook” (I2, T50, L1)

“Well, I think it’s about not being so strict, not being so punishing to yourself if things go wrong... you know that thing about ‘it’s OK’? It’s OK because sometimes it won’t go right, sometimes you will get, you know, high levels of blood sugar, an awful day or an awful year and you’ll just be sick to death of it. But you can... you know, not to give up because you can’t achieve perfection, you just try. And come back to it again, start again...” (FG, T114, G10, L1)

Notably, self-compassion is being described as an antidote to perfectionism which was the researcher’s intention in including and emphasising it in the intervention. The combination of self-compassion, being present in the situation even if your diabetes self-management is not going to plan and having acceptance for the situation seem to be relevant to G10’s ability to overcome resentment and stuckness in her diabetes self-care.

Perfectionism

Perfectionism was not one of the mechanisms cited by the participants as bringing about positive changes. Rather it was framed as being a maladaptive coping strategy that the intervention has helped the participants become aware of and overcome. However,

evidence that it is an issue for the participants will be discussed here since it is thematically entwined with their discussion about the helpfulness of self-compassion.

People with diabetes are often invited (by healthcare professionals, their loved ones and themselves) to engage in an all or nothing struggle to perfectly control their blood sugar levels and their lifestyle. Illustrated here by I2's discourse about getting it right, failure and achievement:

"I'm sure that's how I approach everything in life. I think I probably like to be given, 'this is what you do and this is the way you do it, and if you don't do it you're failing and if you do do it you've achieved...' I think even when I go and see [my endocrinologist] and I show him my [blood sugar] readings, I feel like there's a wrong and a right way." (I2, T16, L1)

The consequence of not 'getting it right' is the threat of diabetic complications and premature death. However, diabetes cannot be perfectly controlled or as I2 expressed it, "You can't get hold of it, ever." Hence, the strategy of trying to perfectly control your diabetes all of the time is doomed to failure and consequent feelings of anxiety and fear (of complications), guilt ('it was my responsibility, I've failed, what will my doctor/mother think?'), anger, powerlessness and low mood. Feeling a failure can also become internalised and affect feelings about themselves or their bodies. In response to developing diabetes G10's reaction was, "I felt like my body had failed and "I must whip it into shape" (VC, T16, G10).

Many of the participants came right out and stated that they were perfectionists, for example G2, “I want things done well, I’m a perfectionist.” (G2, T15, L1). I2 was both aware of her perfectionism and that it was making life harder for her as a diabetic, “I think it [diabetes] is a disaster for a perfectionist” (I2, T50, L16). She went on to explain:

“I think being diabetic probably made that[being a perfectionist] worse because it never leaves you. You see you’re always, even subconsciously thinking, oh my blood sugar is... should I be doing this? should I be doing that? am I able to have half an hour a day without having to think about it... So I think that’s added to that feeling. And I’m sure that does make me feel more stressed... That was an aspect of my personality and the diabetes has really sort of gone into that and made it worse.” (I2, T26, L6)

I2 mentions that she feels the perfectionism predated the diabetes but that the diabetes exacerbated the perfectionism. Whether or not the pressures of coping with diabetes lead to a perfectionist thinking style there seems to be evidence of perfectionistic thinking being overgeneralised in some of the participants. For instance I1 describes applying that thinking not only to what she is doing but what she is feeling:

“I think I spend all my time trying to tell myself that I should be something, or that I should be feeling this way, or I should be doing that. And then if I’m not, then feeling terrible about it... and ninety-nine percent of the time I’m not doing that thing.” (I1, T18, L2)

The researcher predicted that this over extension of perfectionism to all aspects of life might cause difficulties during the intervention. For example, if we had asked the

participants to practice the mindfulness exercises every day for forty-five minutes and they were unable to that this might have triggered their perfectionism leading to feelings of failure and guilt. Hence, we deliberately only suggested (rather than prescribed) ideas for home practice. Unfortunately, despite this G2 still seems to have become perfectionistic about her level of mindfulness practice:

“With the mindfulness I’ve got to do it more, no one can do it for me. The trouble is I’ve never felt that important, I’m too strict on myself and not kind to myself, I can’t allow myself any weaknesses.” (G2, T54, L1)

She also demonstrates here a thematic link between lack of self-compassion and being hard on yourself (perfectionism). It is perhaps salient that she did not attend the session that was explicitly on developing self-compassion.

Feeling Less Guilty

I2 refers to the guilt that results from the failure of her perfectionistic strategy:

“I do feel guilty a lot of the time that I’m not achieving things that I should be achieving.” (I2, T36, L1). G1 talked about mindfulness as being a coping skill that allowed her not to feel guilty when she chose not to follow the diabetes self-management guidelines to the letter:

“it’s made me feel comfortable when I have gone out and enjoyed St Patrick’s Day and felt guilty. It’s another coping skill. Now instead of feeling guilty and then for the next three weeks thinking I mustn’t eat this and I mustn’t drink that, I’ve got to be careful, I’ve enjoyed it, I’ve moved on, I’ve relaxed, and I’m looking forward to next St Patrick’s Day which I wouldn’t have done last year.” (FG, T124, G1, L1)

G10 spoke of an attitude shift that had come about through taking part in the intervention that enabled her to just get on with her self-care tasks, which relieved her feelings of guilt:

“in a way to be aware that wouldn’t it be simpler just to do these things[diabetes self-care tasks]? And when you do, you know like get good results or whatever, you know, the burden, the guilt, that’s lifted, it’s just extraordinary.” (FG, T34, G10, L13)

Mindfulness as a Tool to Control Diabetes

In order to try to avoid invoking the participants perfectionism and adding to the number of self-management tasks they had been prescribed the facilitators were keen to avoid implying that mindfulness could be a tool to help them manage their diabetes. Interestingly, some participants did come to view it in this way and did not find this an unhelpful way of experiencing mindfulness:

“as well as taking the blood and eating right and exercising, three meals a day and water, this is another tool to control it [diabetes].” (FG, T122, G1, L6) and:

“Or it [mindfulness] is going to be another thing in my sort of armoury against it [diabetes].” (I2, T66, L1)

In fact a theme about needing to control diabetes and diabetes being in control of you emerged. For example G8, “with the diabetes I hate to, you know, not to be in control of it” (FG, T28, G8, L13) and I2, “And it [diabetes] made me feel out of control. And I think I’m a control freak.” (I2, T62, L1). G10 talked about her “resentment” towards

diabetes. Here she explains why she feels resentful, which had blocked her from doing diabetes self-care tasks and how mindfulness has shifted her attitude towards self-care:

“I previously thought of diabetes as having wormed in and invaded my pancreas and I didn’t consent to any of it. And I didn’t agree to this. I saw it as something powerful that had control of me that had overwhelmed me. Now I think I live in this body and I might even check my blood because I’ve a mind to, not because diabetes says so.” (VC, T9, G10)

Awareness of Body, Wholeness

The awareness of inhabiting a body was very important to G10. G5 believed that a shift in her relationship with diabetes came about because the mindfulness taught her to listen to her body.:

“It makes you think about what your body does, not what your doctor keeps telling you to expect or society or television, but what your body wants you to do. It’s a different way of thinking about it” and “It’s listening to what my body was saying”

G10 also spoke about the wider impact of the programme on her outlook and relationship with herself that allowed her to feel whole and relieved her fear:

“Finding a truth about yourself and something has changed in me, it’s not about being happier. If you’ve got that in you, you can hold onto it and feel less fragmented and afraid. It’s precious I spent 10 years being frightened.”(VC, T20, G10)

Effect of Being in a Group

All the participants reflected on what it had been like to do the intervention either with other PLWD or as an individual. For most group members the experience of being in a group had been positive, with many people attributing the benefits to group processes rather than or in addition to mindfulness. For example G3 attributed the fall in his blood sugar readings to group factors:

“I’ve been five years on double figures. You know, something has caused it. And if it’s just coming along, being in pleasant company, it could be something as simple as that. But one has a day a week when one is able to totally relax with the people who are also diabetic. That in itself might be the reason.” (FG, T58, G3, L1)

Choice about whether to receive the therapy as an individual or in a group was important to some participants. I2 was worried about being with other diabetics and perhaps seeing evidence of diabetic complications that she did not yet have. “And this added fear that I have of other people who are diabetic” (I2, T72, L5). G2 realised through taking part that group therapy was not a good fit for her:

“Being in the group was hard and not helpful for me. I’ve always solved my own problems in life and I haven’t relied on anyone else before. The group personally made me feel, not shut off, but not wanting to join in.” (G2, T36, L1)

On the other hand G2 found that attending the group made her feel less alone with her diabetic problems:

“I tend to think I’m alone with it and then feel lonely. It breaks it to know other people have similar problems which breaks the loneliness.” (G2, T52, L1)

Many group members talked about the importance of discovering similarities with other participants and the relief this brought:

“when people talked about not coping it made me feel better ‘cos they do things I do (like putting off things til tomorrow). I suppose I felt less of a failure when I heard that other people use the same tricks with diabetes as me. Just realising how strongly it affects people and what a big burden of energy they experience in trying not to accept it. It felt like an enormous burden, a shadow, was draining away. A big black shadow across ¾’s of my life and to go on for years...” (VC, T8, G10, L3)

G10 also referred to the interaction between mindfulness and doing mindfulness in a group:

“Then having a group, it sounds so peculiar what happens with mindfulness. Doing mindfulness in a group of strangers who do this very intimate thing and a process happens in the room where things get stripped away.” (VC, T8, G10, L9)

G1 also reflected on the value of having mindfulness as a group task:

“It was good that it was not just talking about diabetes, that would have been too heavy we needed the other dimension because the self-care stuff was so hard. Mindfulness took away the heaviness gave a something else. It was about meeting others that were not just diabetics. That helped I possibly wouldn’t have come to a diabetes support group per se. I didn’t want to come to something that was just about diet and exercise.” (VC, T14, G1, L1)

It seems one effect of having the focus on mindfulness rather than diabetes was to lessen the anxiety around dealing with diabetes and allow people to take part in the group.

Another important aspect of the group process was the experience that the group expressed compassion to one another:

“I suppose I just felt there’s a great deal of compassion and kindness at times.” (FG, T110, G10, L13)

However, one aspect of group members feeling concerned about each others well being was that some group members ended up ““feeling worried and responsible for peoples well-being when people dropped out of the group” (VC, T12, G1). This will be important for the facilitators to pay attention to in future groups

4) Negatives of the Intervention?

It was felt to be very important to enquire about any negative effects of the intervention since it had not been offered before. In addition there is no clear literature on the negative side effects of mindfulness or the types of problem it is unsuitable for.

The main negatives mentioned were to do with having to fill in the research measures and have been discussed during the presentation of the results of the quantitative measures. One aspect of evaluating the suitability of the measures was to reflect on the process of administering them and to listen to the participants’ experience of completing them. The facilitators’ impression was that the weekly measures in particular were

disruptive to the group's process. For instance, despite being only 5 items long, in order to get everyone present to fill in the WHO-5 it took twenty minutes of each session.

The participants discussed the measures in their interviews. A group member reflects the general feeling of resistance to completing the questionnaires in this statement:

"The other thing was paperwork. I'd rather just say something than... It's helpful to everybody who's organising the course, but I didn't want to do that. I just wanted to say what I wanted to say, and not think about it." (FG, T86, G1, L1).

In addition G3 and G8 had concerns about how valid and reliable the information captured by the measures was, G3 talking about the WHO-5 said:

"You've got five questions here which really, in my mind, can give a very very false picture." (FG, T168, G3, L1)

G8 added:

"I suppose we need to fill these things just while things are fresh in your mind, but I did find at times I was filling things in, in a very haphazard way." (FG, T177, G8, L1)

Conversely one participant (I2) found the weekly measures helpful:

"I did find the questionnaires helpful in a way to reflect on the week that had been"

Overall the questionnaires were less acceptable to the participants than the intervention itself and the time involved in their completion called into question the feasibility of using weekly measures in the group intervention in future studies. Since it is likely that quantitative measures will be used in the next stage of evaluating this intervention a different way to help participants approach them needs to be found. It is also possible

that modifying the questionnaires or changing some of them in line with the participants feedback will make using them more acceptable to the participants of future research.

Other negatives about the intervention included, the duration of the intervention. For example, C1 felt that the intervention had not been long enough for her, however she also said she had got enough to keep going on her own. G10 reported feeling self-conscious meditating in the group. She also talked about feeling distressed during meditation practices, however, she was able to work with this and viewed it in a positive light, as part of her spiritual journey:

“the meditation, I’ve just found... I mean at times I’ve found it very difficult to do because... because I feel very upset. It depends what we’ve done. And some things have just upset me greatly and um... And I’m quite pleased with myself actually. I might be going to some kind of spiritual place or some place which is about finding – who you are or something. There’s a place where you could go to, a kind of silent place. That’s actually quite scary.” (FG, T34, G10, L20)

This highlights that future facilitators should be mindful of the participants’ response to the practices and help them to use mindfulness and compassion to allow and to bring meaning to their distress.

I2 helpfully pointed out that different individuals have different responses and objections to the different mindfulness exercises:

“some of the techniques suited me and some didn’t. We were laughing about the raisin one because when you work with children, you never eat anything without washing your

hands because you know you're going to be ill. So the raisin threw me completely because I said to Sonya, I'm really sorry but I can't eat it." (I2, T84, L12)

This may also relate to the Buddhist idea of 'skilful means' whereby meditation practices enable you to get to know your mind and which mindfulness practices are most beneficial to you in which circumstances.

Results of Validity Check for Qualitative Analysis

The majority of divergences in terms of classification of themes and quotes to illustrate themes occurred when particular quotes illustrated a range of closely related constructs or categories such as acceptance and self-compassion. There was a divergence in emphasis in the categorisation of the themes into larger categories whereby Reader 2 (R2) placed the reversal of avoidance and recognition of the impact of perfectionism under a larger category of 'identifying and overcoming the impact of unhelpful coping or self-management strategies'.

Primary differences in the interpretation and classification of material related to the difference conceptual resources informing the two researchers interpretation of the material. It was noted that the author (Reader 1 – R1) made use of more holistic, spiritual concepts derived from her knowledge of Buddhist psychology and philosophy than R2 who made use of cognitive-behavioural models derived from health and clinical psychology. For example in the *Awareness of Body, Wholeness* section R1 interpreted G10's statement about mindfulness enabling her to feel less fragmented and less afraid

in a Buddhist philosophical framework. In the Buddhist view one of the most important benefits of meditation is that it “brings the mind home” (Sogyal Rinpoche, 2002) giving a holistic, embodied experience of self versus one’s usual fragmented scattered sense of who we are. R2 interpreted the same quote as an example of the benefits of an increased sense of the physical self not being so separated from the mental self. The readers compromised by emphasising the benefit of wholeness and leaving out the Buddhist interpretation. The discussion between the Readers highlighted some of the difficulties in discussing these concepts within our existing Western Psychology viewpoint where a much less rich vocabulary exists than in the Tibetan Buddhist context with which R1 is additionally familiar.

Discussion of Qualitative Results

Summary of Qualitative Findings

The benefits of the interventions derived from the interviews were: it was calming, helps you deal with emotions (anger, resentment, anxiety, fear and guilt), helps you get off to sleep, being able to cope with medical procedures, results in you having a more compassionate relationship with yourself and a more accepting relationship with diabetes. Specific benefits relating to diabetes were that: many of the participants reported that their blood glucose readings were lower by the end of the intervention, and that they were checking their blood glucose levels more often, having less diabetic pain (and needing less medication for pain) and feeling less guilty after going off track with self-management tasks. The main negatives about the intervention and evaluation were filling in the research measures, feeling self-conscious, wanting a longer intervention and feeling distressed during meditation practices.

The Benefits of the Intervention

In line with the Grossman et al (2004) the participants have noticed benefits including improved coping, reduced anxiety and improvement of their medical symptoms including pain. One of the diabetes specific benefits noted by the participants was lower blood glucose readings and/or lower HbA_{1c} readings at their next diabetes clinic visit. The mechanism by which mindfulness might lead to better glycaemic control is unclear. Riazi et al (2004) investigated the relationship between daily stress and glycaemic control over 21 days in 54 people with Type 1 diabetes. They discovered that a third of

their sample showed a significant association between stress and same or next day blood glucose levels (they called this group ‘stress-reactive’). Riazi et al (2004) propose two mechanisms by which psychological stress might affect metabolic control in Type 1 diabetes. Firstly, by a direct psychophysiological effect, stimulation of the sympathetic nervous system and pituitary gland resulting in raised levels of catabolic hormones leading to increased blood glucose levels. Secondly, stress results in behavioural responses which disrupt self-care and lead to raised blood glucose levels. For example, increased compensatory and comfort seeking behaviour such as eating more high carbohydrate foods, drinking more alcohol and be more sedentary. Also, perceived time urgency can make blood glucose monitoring less of a priority. On the basis of these ideas it could be hypothesised that mindfulness might improve reported glycaemic control by reducing physiological responses to stress (by being “calming and relaxing”), reducing anxiety (or perceived stress) and by helping people get back “on-track” with self-care tasks by reducing guilt

Potential Mechanisms for the Benefits

Themes concerning the participants own ideas about how the intervention helped them were derived. These themes related to the following possible mechanisms of mindfulness and self-compassion bringing about beneficial effects: reversing avoidant coping strategies, providing a way of coping with negative emotions (anger, anxiety, guilt) and pain, through the development of acceptance and self-compassion, by providing an antidote to perfectionistic thinking styles, by being a tool to manage

diabetes and through enhanced body awareness. Some of these mechanisms are further discussed here with reference to the wider literature:

Reversing Avoidant Coping Strategies:

This was part of the formulation for the intervention that the accepting mindful attitude of turning towards difficulty with openness, curiosity and kindness might help PLWD become aware of and overcome their avoidant coping strategies. Avoidant coping in PLWD has been previously documented in the literature e.g. Turan, Osar, Turan, Ilkova, Damci (2003). In the study by Riazi et al (2004) examining the relationship between stress and glycaemic control in diabetes it was found that the stress-reactive group could be discriminated from the non-stress-reactive participants by their coping strategies. The stress-reactive group were more likely to employ emotion-focussed coping strategies (which include becoming self-preoccupied and avoidant coping). In their study, for the stress-reactive individuals, emotion-focused coping was associated with more stress and higher blood glucose levels. In the current study stress reactivity was not measured, however, this may provide another explanation for the participants' observations of improved glycaemic control post intervention i.e. shifting from avoidant to active coping strategies is associated with better self-care, less stress and lower blood glucose levels.

Counteracting Perfectionistic Thinking Styles

There is little mention of perfectionism in the literature for PLWD, the exceptions being Basco's (1998) discussion of the difficulties it causes for self-management and relationships with health-professionals (see introduction) and Pollock-BarZiv & Davis (2005). Pollock-BarZiv & Davis (2005) look at the presence of eating disorder

symptoms in 51 women with Type 1 diabetes and include measures of cognitive factors such as perfectionism. Neurotic perfectionism represents maladaptive aspects of a desire to be perfect, including “setting unrealistic standards and stringent self-evaluation,” and is now recognized as a major predisposing factor in the development and maintenance of eating disorders, Pollock-BarZiv & Davis (2005). They did not report a significant difference in neurotic perfectionism between those women with adequate and poor glycaemic control. However, neurotic perfectionism was significantly higher in the group with eating disorder symptoms than those without. This is a small scale study and not an attempt to investigate the relative prevalence of neurotic perfectionism in the diabetic population or its relationship to glycaemic control. It would be very helpful to further investigate both these questions since there is some suggestion from clinician’s e.g. Basco (1998) and our participants that perfectionism is a factor in poor self-management of diabetes. In any case, cognitive distortions in PLWD would be a helpful area to conduct more research with a view to better understanding the distress and self-management difficulties for PLWD. Following Clark’s model (2004) this would also be an initial step towards designing a new cognitive therapy intervention for PLWD with self-management difficulties.

Group Processes

Given that MBSR and MBCT are group treatments it is perhaps surprising that little has been written about group processes in mindfulness-based approaches. The exception being Chadwick, Newman Taylor and Abba (2005) measured therapeutic factors based on a model by Yalom in order to ascertain the relative importance of mindfulness as a therapeutic process in their mindfulness groups for people with psychosis. Yalom (2005)

argues for a 'pluralistic approach to psychotherapy' whereby a therapist would integrate helpful aspects of other approaches to therapy. The rationale for this with therapies delivered in a group is, "all groups, even the most structured ones, also have a group process that may impact the group. You may determine that it is outside the scope of the group to explore directly that process in depth, but you must be able to recognise its presence and how best to utilise, manage, or contain it." (pg. 480, Yalom, 2005). Universality is one of the group therapeutic factors he describes. He points out that people come into group therapy feeling unique in their problems and inner experiences. Yalom proposes that "disconfirmation of a client's feeling of uniqueness is a powerful source of relief" (pg. 6). Altruism is another of the group therapeutic factors cited by Yalom (2005). He points out the group therapy is the only form of therapy where clients have the opportunity to benefit other people. It is possible that the participants were able not only to develop loving kindness for themselves but also to express compassion towards other participants in the group and that this in itself may have had a therapeutic effect.

The Methodology

The methodology of the qualitative arm of the study has been heterogeneous using both individual and focus group interviews, however this is not unprecedented as it was used by Braun & Wilkinson (2005) in their qualitative study of womanhood. For brevity only the themes directly relevant to the research questions have been presented here. The additional material further elucidates the formulation for the intervention and so will be written up for publication separately. It would be possible to analyse the transcripts in other ways which might also provide interesting data. For example the interactions

between participants in the focus group have not been considered in this thematic analysis.

Considering Elliot et al's (1999) guidelines for enhancing validity of qualitative research most of the points have been incorporated into the design. However, the following methodological caveats should be raised: the positioning of the author as facilitator and researcher might be problematic. Awareness of this (which we tried to minimise) amongst participants could have made them reticent in expressing negative views in the interviews. This was why an independent moderator facilitated the focus group and the other researcher interviewed the individual participants. However, it places the researcher in a difficult position to offer an unbiased appraisal of the intervention and evaluation data. Two forms of validity check for the interpretation of the qualitative data have been provided, an audit by an independent reader of the analysis and the presentation of the themes derived back to the focus group who agreed with them all. The researcher has also provided examples of the analysis process in Appendix 7.

Triangulation has also been used in the study to explore the participants response to the intervention using quantitative measures as well as qualitative interviews. The initial description of the participants and their relationship with diabetes, difficulties with self-management and experience of psychological distress could have been made richer by conducting a pre-intervention qualitative interview in addition to the post interviews. However, post-intervention all but one of the participants who completed the programme have been interviewed and provided quantitative data. It is hoped that the

presentation of results is coherent, believable and has helped to make sense of the participants' experience of the mindfulness for diabetes intervention.

Answering the Research Questions

The study has enabled us to report the perceived benefits of the intervention. The only negative effect of practising meditation was feeling very distressed during the practice. However, the participant who had this experience viewed this as being a part of a spiritual journey. The majority of the benefits were attributed to the mindfulness and compassion practices. However, the compassion experienced from other members of the group and other group processes such as universality were cited as being as important as formal loving kindness practice in bringing about benefits (at least on a conscious level). Given that mindfulness-based approaches have traditionally been offered to groups it seems sensible to consider the effects of group therapeutic factors and to try to encourage them in future groups. As Yalom comments it is not possible to offer group treatments without group processes arising so it seems appropriate to understand how they interact with mindfulness and compassion practices and to make use of them. As discussed one participant (G8) was attracted to the intervention because it was a therapy group rather than because it was based on mindfulness and found it beneficial because of the group processes. Now that the study has been carried out and no negative side-effects have been reported this seems to be a legitimate reason for taking part in the intervention, particularly because at present the service does not offer any other group psychological approaches to self-management or coping with diabetes.

In general, it seems that the intervention enabled the participants to relate differently to diabetes, to themselves as diabetics and towards their self-care tasks. They became able to face up to the reality of their situation (rather than avoid it) and came to feel more accepting and compassionate towards it and themselves. All of which enabled them to make some positive changes to their diabetes self-management, for example, checking their blood sugar more frequently and quitting smoking. The main aspect of the intervention which the participants were unhappy with was filling in the research measures.

Conclusions

Answering the Research Questions

The intervention was found to be acceptable and beneficial to the participants and it was feasible to run in the clinical context in which it was investigated. No serious side-effects of practising mindfulness and compassion were reported. However, it remains a possibility that participants found this hard to discuss at interview or that some of the dropouts left the group because of negative experiences.

How well did the Quantitative Measures Capture the Benefits Described?

The study has mainly addressed the research questions through its analysis of the qualitative data. As this was a pilot study evaluating the outcome of a new intervention it was not known what the main benefits and difficulties would be. The quantitative self-report measures were included in a speculative manner to try to assess whether they reflected any of the main changes reported by participants in the qualitative interviews. It was hoped that the qualitative and the goodness of fit with the quantitative findings would guide the selection of outcome measures for future stages of the evaluation of the intervention.

The largest change noted in the quantitative results was a relatively large drop in diabetes related distress on the PAID measure. This measure has items concerning acceptance of diabetes and feelings of guilt when off task with self-management of diabetes which triangulate well with some of the benefits noted in the qualitative analysis. One group of themes within the coping with emotions cluster of the qualitative

analysis concerned overcoming anxiety and the scores on the HADS-A changed very little which did not seem to reflect this perceived change (mentioned by three participants in their qualitative interviews). It is possible that most of the anxiety which was overcome was related to diabetes and so was captured by the PAID.

Overcoming low mood was not described as a benefit in the qualitative interviews and depression and well-being scores changed little over the course of the intervention, this again seems to triangulate well between the qualitative and quantitative measures. In future studies it might be appropriate to replace the WHO-5 weekly measure with a shortened form of the PAID.

Benefits such as being calming, getting off to sleep, coping with medical procedures were not captured by the quantitative measures. The mindfulness and self-compassion measures might come into their own in larger scale evaluations when changes in behaviour and distress could be related to changes in compassion and mindfulness. As it stands the MAAS demonstrated a small increase in mindful awareness showing that the intervention might be having some effect in increasing its target mindfulness. The self-compassion measure only showed an increase after the loving kindness practice had been introduced perhaps indicating the importance of including it in addition to emphasizing the self-compassion inherent in practising mindfulness in general.

One of the main self-management benefits noted by the participants in their interviews were quitting smoking which did triangulate with a drop in number of cigarettes smoked on the self-report measure. In addition some of the participants spoke about discovering

that their HbA_{1c} levels were down at their next clinic visit after the intervention which they attributed to the intervention. The self-report measure indicates small improvements in self-management from start to finish of the intervention in the domains of diet, testing blood sugar and foot care. HbA_{1c} scores could be thought of as reflecting the aggregated level of self-management over the past three months and so might reflect a real improvement in self-care. However, one of the shortcomings of this study is that blood glucose levels were not directly measured to provide a more valid measure of this variable. The researcher decided not to measure blood glucose directly for fear of invoking the same psychological responses to being monitored in the participants as they have in the diabetes clinic (evaluations of having failed and feelings of guilt, anger and helplessness) and thereby disrupting the participants engagement with the intervention. However, the observations of the participants themselves would provide a mandate for sensitive monitoring of blood glucose levels in future evaluations of the intervention. This would enable the validity of the participants self reported improvements in diabetes self-care and glycaemic control to be measured.

Methodological Issues

Alternative Explanations of the Findings

Elliott (2002) describes a variety of validity threats to single case studies these include:

Non-improvement – on some measures (anxiety, depression, self-care) there appears to be non-improvement although in the qualitative descriptions of benefits improvements for well-being, anxiety and self-management behaviours are described)

Relational artefacts (the results may be due to the participants attempting to please the researcher rather than actual change. This is an issue for this study since the researcher was also one of the therapists).

Client expectation – change could just reflect client expectations of getting better as a result of taking part. The researcher suspects this may have occurred in the case of participant G3's giving up smoking or that may have been due to :

Self-correction – where change is due to participants self-help efforts rather than the intervention or could be because their problems were short-term or went into remission (e.g. depression).

Extra-therapy factors – e.g. forming a new relationship, getting a job, could have brought about change rather than the intervention

Psychobiological factors – for example starting a new or different course of medication might be responsible for symptom relief rather than the intervention and the participants were only asked to report their medication use before the intervention.

Reactive effects of research – change could have resulted from just taking part in the research and increasing self-monitoring (e.g. possibly the improvements on the foot-care scale because participants mentioned in the group not having been given specific advice about foot care and the questionnaire itself forms a check list of how to care for your feet)

Some of these methodological issues can be resolved by designing the study differently, measuring more variables, separating the therapist and researcher roles, or using random allocation to treatment and comparison intervention arms.

Designing the Next Phase of the Study

Overall this study has been successful in its aims of exploring ways to evaluate a new psychological intervention for people with self-management difficulties with their diabetes. The participants found the intervention acceptable and beneficial, no negative side-effects were found and it proved feasible to offer the intervention in the clinical setting. Therefore, there is a mandate to continue to develop the intervention and the evaluation process.

It would be helpful to develop the formulation for the intervention further. This could be done by exploring the cognitive biases and the emotional impact of living with diabetes using questionnaires. Clark (2004) suggests that working out the cognitive biases is a pre-requisite of designing a new cognitive therapy intervention. The next step for the evaluation of this intervention might be to conduct a larger scale pre and post design study to begin to check the validity of these findings. It would be an improvement to conduct qualitative interviews before and after the intervention (again to find out about the experience of living with diabetes and a description of the persons current difficulties). Adding an objective proxy measure for effectiveness of self-management (such as HbA_{1c}) would also strengthen the evaluation. It would make sense to confine measures of low mood and anxiety to the screening participants stage and to change the weekly measure to a brief measure of diabetes related emotional distress. A larger scale study would enable statistics to be used and these could be used to explore the relationship between levels of mindfulness and self-compassion and the outcome

measures. Finally the outcome of receiving the intervention as a group member versus an individual client could also be compared as part of a larger study.

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Part 3

CRITICAL APPRAISAL

CRITICAL APPRAISAL

Introduction

I hope to use this paper as an opportunity to reflect on the process of designing the intervention, conducting the research and presenting the study. It will also offer a chance to describe some of the decisions which have been taken during the study and writing up process and to extend the discussion presented in paper 2.

P1 Expansion of Discussion

strengths and weaknesses of the research

A small N design was used to conduct an exploratory evaluation of the mindfulness for people living with diabetes (PLWD) intervention. This type of small scale design was chosen because the intervention had not been tried before with a group of PLWD so it was not known at the outset whether the intervention would be helpful or whether it might have negative aspects. It was therefore felt to be more ethical to start with a small trial. It was also important to invite the participants to self refer, to screen them carefully to exclude people likely to have adverse reactions to mindfulness at that point in their lives, to provide them with as much information as possible and be very honest with them about the newness of the intervention to allow them to make an informed decision to participate. A strength of the study is that some criteria for evaluating the validity of small N research were selected and used to judge the validity of the evaluation (Elliot, 2002).

The design of the study is also appropriate to the stage of the research question and to the research questions being answered. However, it is not a design which can answer questions of causality. This is a cause of frustration when colleagues and other PLWD served by the team ask about the benefits of mindfulness. However, we and they remain enthusiastic about continuing to evaluate the programme to find out whether the benefits reported to us were the result of mindfulness rather than other causes (such as self-help, trying to please the researchers, changes in insulin regimen, etc).

A mixed methodology (incorporating both qualitative and quantitative methods) was employed. This was done from the standpoint of methodological pluralism, which appreciates that all research methods have flaws. In order to increase validity it is helpful to choose appropriate methodology for particular research questions and to triangulate the data gathered from different perspectives. Collecting quantitative and qualitative data from the participants was also a way to enrich the data gathered on a small number of people. However, juxtaposition between the qualitative approach (acknowledging the inherent and inescapable bias of the researcher, prizing the unique experience of the participants) and quantitative approach (emphasising the objectivity of the researcher, the standardisation of methods and the replicability and generalisability of findings) caused some difficulties in writing a report with a unified style.

The debate between researchers who use quantitative and qualitative methods is an old and often acrimonious one, which is based on epistemological differences. The researcher had to consider this in planning, making sense of the results and writing up the study. Ontological differences between the two major paradigms revolve around the

perceived nature of reality. Whereas positivists believe in a single reality that can be measured reliably and validly using scientific principles, interpretivists believe in multiple constructed realities that generate different meanings for different individuals, and whose interpretations depend on the researchers lens (Onwuegbuzie & Leech, 2005). Epistemological differences between the two paradigms are based on the relationship between the researcher and participant, positivists espouse separation between subject and object, whilst interpretivists maintain that the two entities are mutually dependant and that this should be used to understand phenomena. Axiological differences concern the role of values, positivists believe that research should be value free, interpretivists think that research is to a great extent influenced by the values of the researcher. All this caused stylistic difficulties in writing up the two arms of the study based on different assumptions about the positioning of the researcher and the different systems of checking the validity of the data. Separate criteria for establishing validity of each arm of the study were described and applied to their respective arm of the study.

However, the pragmatist view of research emphasises the similarities between the paradigms. Onwuegbuzie & Leech (2005) point out that regardless of epistemology all research in behavioural and social sciences attempts to understand human behaviour and is therefore unified by its intent. In addition, both paradigms use research questions, analytic techniques to find meaning, techniques to verify data and data-reduction methods.

One thing which struck the research was that despite having only 10 participants the use of mixed methodology resulted in a very rich and complex data set. Some of the data

presented has had to be simplified for the purposes of presentation in the thesis, for example only commenting on the mean quantitative scores and scores on the component scales of the self-compassion scale were not reported. Only the themes derived from the qualitative material which answered the research questions were presented. Whilst all those concerning negative aspects of taking part were reported, those covering the parts of the intervention which were particularly valued by participants were not. These will be used to guide the facilitators in deciding whether and how to refine the intervention. In addition, the researcher kept a wealth of process notes during the intervention which have not been presented. This might have added another perspective to the data collected from the participants on what were the more helpful and hindering aspects of the programme and on the mechanisms of how mindfulness and compassion brought about change.

The study produced was very much a product of the clinical context in which it was conducted and the design evolved with the real world concerns of the participants. As some people were unable or unwilling to take part in the group it was decided to evaluate them as individuals receiving the same intervention. However, since this was not a feature of the original design it was not possible to formally compare the merits of receiving the intervention one to one versus in a group. This could be investigated in future studies perhaps randomly allocating participants to group or individual therapy. The researcher was able to reflect on the difficulties inherent in trying to deliver a standardised therapy protocol in different settings and with different individuals. It was hard not to respond to the individuals differently and to adapt aspects of the programme (for example showing I2 how to meditate with her eyes open since this was her

preference however it was not shared by any of the other participants). It was also frustrating not to be able to use the weekly feedback from the helpful aspects of therapy (HAT) forms to change the level of explanation or pace of the course as we might have when not following a predetermined protocol.

One of the main methodological concerns with the study was not being able to conduct more in depth interviews with people who chose to leave the intervention early. This problem with lost information from dropouts is common to all research and a stipulation of participants' consenting to take part is always that they can leave at any time without stating a reason. However, in this study it was of particular importance to establish the safety of the intervention by documenting any adverse effects of taking part. It remains a possibility that some people left because of negative experiences during the mindfulness practices.

In terms of the qualitative arm of the study the positioning of the researcher as clinician and analyser of data may have been a strength in terms of being close to and understanding the data generated or a weakness in terms of inhibiting the participants in expressing their views freely even through another facilitator. "*Reflexivity*" allows a qualitative researcher to address subjectivity, exploring emotional investments in the topic, focussing on the position of the researcher, and making moral-political standpoint clear (Wilkinson, 1988). In terms of the analysis I wonder whether there is a difference between being able to identify themes due to shared understanding and unconsciously filtering out disconfirmatory ideas due to emotional investment in the success of the

intervention. It was therefore important to enhance the validity of the analysis by having another researcher audit it.

The focus group transcripts could have been analysed using other styles of analysis to look at constructs like social construction of meaning within the group or group interaction. There were incidents of disagreement as well as individuals asking other questions and empathising with one another within the focus group session which might have provided interesting information about how the participants came to understand mindfulness.

Not all the themes derived from the thematic analysis could be presented in the thesis so it was decided to present those which answered the research questions. The additional themes were: relationship with diabetes (which had sub-themes about emotional reaction, causation and self-blame, history of relationship with diabetes and how the intervention has shifted the relationship towards acceptance), How self-care feels like an external imposition and how not getting it right sets off their perfectionist schemas leading to coping strategies like avoidance, their relationship to help (issues with the NHS, feeling judged by healthcare professionals, avoidance, after the intervention having compassion for the healthcare professionals and their impotence in being able to treat them as diabetics), relationships with others (taking care of the needs of others before yourself –women only – and how mindfulness has shifted this to discovering and attending to own needs as well, not wanting to let others in on the secret of mindfulness, working with anger in interpersonal situations). Many of these themes relate to our formulation of the problems of self-management in diabetes and how mindfulness and

compassion might help. It would therefore be worth exploring these further in future studies. We wondered as well whether the method of recruitment itself helped to reverse our participants reluctant relationship to help by allowing them to recognise a problem for themselves and take responsibility for coming forward for help (which admittedly they could leave at any time without sanction).

Clinical Implications

In summary, what has been achieved is to start to formulate an understanding of why PLWD have difficulty in self-managing their diabetes which has been shown to be absent from the literature. A mindfulness-based intervention has been specifically adapted for PLWD for the first time. The study has taken the first step in evaluating the acceptability, feasibility, benefits and safety of the intervention for PLWD. The intervention shows potential for shifting the relationship to diabetes towards a more accepting compassionate one. It also seemed to have the effect of decreasing emotional distress related to diabetes and increasing the positive pro-health behaviours of the participants, all of which are important clinical implications.

Since low mood and non-diabetes anxiety did not seem to be changed by the intervention one clinical implication is to screen for depression and anxiety and to suggest that PLWD with those clinical issues seek help for them first or in addition to taking part in the mindfulness intervention to help them with diabetes related issues.

P2 Personal Reflection on the Research Process

This project is the culmination of three years of work as I first met with my supervisor in the first month of training. Having already conducted a large quantitative study for my previous PhD I was keen to take on a piece of research which I found meaningful and which I knew I could stay enthusiastic and engaged with for three years. I therefore set out to combine my Buddhist background and interest in mindfulness-based therapeutic approaches with creating a D.Clin.Psy research project. I was fortunate to meet my supervisor at a time when he was also developing an interest in mindfulness and was looking for ways of helping PLWD with self-management problems. He and the UCL course staff have made me aware from the beginning that conducting intervention research for a D.Clin.Psy project is ambitious.

I have enjoyed and learnt a lot from the process of reviewing the existing literature, finding knowledge gaps, doing clinical work with PLWD and developing a clinical understanding of their problems, formulating their self-management difficulties and adapting the mindfulness programme for PLWD. This framework of working seems to fit within the scientist-practitioner model and through tackling the project explicitly in this way I feel convinced by it as a way of working clinically. As a continuation of the scientist-practitioner model we devised a way to evaluate the intervention. This involved understanding the different stages of research, how to formulate research questions, how to design the study and select methods which could answer those questions. I had also hoped to take this opportunity to learn how to use qualitative methodology. I have benefited from being able to do this and it has seemed to be a good fit with researching the affects of mindfulness which to my mind are inherently subjective and unique to

each person who experiences it. However, it has on occasion been a steep learning curve with my being unable to appreciate some of the finer points of qualitative research which my supervisor was attempting to convey.

The project has faced some setbacks, we hoped to make the group available to the whole population of PLWD who attended the clinic. We felt that offering it in the evening would allow people in full-time employment and parents and carers the opportunity to arrange to come. However, this type of unconventional thinking proved a step too far for the room booking systems at the hospital where we were based so we had to compromise with a late afternoon slot. We allowed three months for R&D and ethics procedures however this took ten months. Various factors were responsible for this including staff leaving their post and not handing on our application to colleagues. Our application coincided with the start of the new COREC system which the staff seemed unprepared to administer. In addition they had never encountered a D.Clin.Psy project before and had no idea of the short timescale involved. Most worryingly, the R&D department's policy was that only a Medic with Consultant in their job title could be the sponsor/lead investigator on an application, thereby disenfranchising all other professions including Clinical Psychology from carrying out research (regardless of this being an explicit part of most NHS professionals job descriptions)! We sought many solutions to this problem including pointing out the unfairness of this policy and many months later it was resolved by a representative from the hospital's medical school advocating on our behalf and offering the medical school as sponsor. We are very grateful for this intervention which seems to be only a temporary solution to the issue.

Due to losing seven months of research time the database of interested people became out of date and we had to begin the recruitment process again. Despite this it has been possible to complete the study in the timescale. However, owing to this and the delays we were not able to include a second group in the study.

Despite all the problems this has been an enjoyable and valuable experience for me. I view all my work as an expression of my Buddhist beliefs and as a way of expressing compassion towards others. It has been particularly meaningful for me to be able to work explicitly towards establishing the efficacy of using mindfulness and compassion based approaches in the NHS. I look forward to the next stage of the research process.

REFERENCES

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APPENDICES

APPENDIX 1
INTERVENTION PROTOCOL

Group Session Plans - Mindfulness for People Living With Diabetes

SESSION 1

Time	Activity	Who
3 - 3:05	Welcome group. Outline the session.	Both Paul
3:05 - 3:35	Short explanation of questionnaires Individually fill in questionnaire pack	Sonya All
3:35-3:40	Toilet break	all
3:40-4:00	Set out confidentiality agreement Agree group conventions (e.g. mobiles off, leave message if you're not coming)	Paul
4:00 - 4:10	Mixer Exercise	Paul
4:10 - 4:30	Mindful Eating exercise (raisin)	Paul
4:30 - 4:35	Enquiry re: mindful eating Autopilot vs mindfulness, Definition of Mindfulness	Sonya
4:35 - 4:40	Proposal to group to become mindful of a regular activity over the week	Sonya
4:40- 4:43	Proposing the hopes & fears exercise	Sonya
4:43-4:50	Filling in Hopes & Fears sheet	all
4:50 - 4:55	Sealing envelopes in jiffy bag ceremony	Paul
4:55 – 5:00	End session	Sonya

SESSION 2

Time	Activity	Facilitator
3:00 – 3:10	Welcome re-cap of names, introduce new people fill in WHO-5	Sonya
3:10 – 3:20	Reiterate Group culture/rules Mixer: In pairs what did you make of last week (pair new people with someone who was there to describe session). Introduce mindful listening	Paul Sonya
3:20 – 3:30	Enquiry: Feedback from mixer How did trying a Mindful activity over the week go?	Paul
3:30 – 4:00	Noticing Thoughts, feelings, sensations: Presentation of CBT model	Paul
4:00 – 4:10	Toilet break	All
4:10 – 4:15	Assemble for body scan	Sonya
4:15 – 4:35	Body Scan – includes gentle introduction to turning towards difficulty	Sonya
4:35 – 4:45	Enquiry: Experiences of the body scan, turning towards difficulty, mind's habitual response to things it likes and dislikes	Sonya
4:45 – 4:50	Proposal: Try doing a body scan this week and/or mindful activity. Hear peoples responses. Hand out CD of Body scan	Paul
4:50 – 5:00	Fill in HAT	Sonya

SESSION 3

Time	Activity	Facilitator
3-3:15	Get everyone into the room, Fill in WHO-5	Sonya
3:15 – 3:35	guided practice mindful standing & then sitting practice	Sonya
3:35 - 3:45	Enquiry: practice	Paul
3:45 – 4:05	Enquiry in pairs using mindful listening : What they noticed during home activities (Body Scan, mindful activity) Feedback to the group, discussion	Paul
4:05 – 4:10	Toilet break	all
4:15 – 4:20	Introducing formal sitting practice : Environment Physical posture Object of mindfulness Mental Posture	Sonya
4:20 – 4:25	Guided Sit	Sonya
4:25 – 4:35	Enquiry: Sit Checking: that method is clear, giving mental posture metaphors, 3 components of mindfulness, balance between alert and relaxed. Tips for regulating dullness/sleepiness & mental agitation	Sonya
4:35 – 4:40	Guided Sit	Sonya
4:40 – 4:50	Enquiry: Sit See points above Autobiography in 5 chapters poem Suggestions for home practice (Choice from mindful activity, body scan, sitting meditation)	Paul
4:50 – 5:00	Fill in HAT, gather files, close session	Both

SESSION 4

Time	Activity	Facilitator
3:00 - 3:10	Welcome Outline the session. remind mobiles off Any questions? fill in Well-Being Qu	Both
3:10 - 3:30	Sitting – Turning towards difficulty, noticing the quality of your internal voice, being kind towards the voice, acceptance Rd Rumi Poem (Guesthouse) during the practice	Paul
3:30 - 4:00	Enquiry re: sitting noticing the quality of your internal voice, Analogies: wise old man, puppy training, giving thoughts space - "the best way to control sheep or cattle". Rumi Poem - welcoming, acceptance, what did they make of it?	Sonya Paul
4:00 - 4:10	Compassion vs commitment and home practice group exercise	Paul
4:10- 4:15	Toilet break	
4:15 - 4:30	Enquiry: What did they try practising at home? What did they notice?	Sonya
4:30 - 4:40	Explanation - Turning towards difficult thoughts & emotions during your day. breathing space	Paul Sonya
4:40 - 4:50	enquiry - Breathing space Proposing home practice choices - one mindful thing a day	Paul
4:50- 5:00	Fill in HAT Qu	Sonya

SESSION 5

Just Facilitated by Sonya (Paul on MBCT retreat)

Time	Activity
3:00 - 3:20	Welcome Outline the session remind mobiles off Any questions? fill in Well-Being Qu & Self Compassion Scale
3:20 - 3:30	Sitting - being like a gracious hostess welcoming all your guests (favourites and trouble makers) in the same way.
3:30 - 3:50	Enquiry re: sitting Enquiry: home Practice (especially breathing spaces) Changing behaviour which has become a habit
3:50 - 3:55	Toilet break
3:55 - 4:00	Settle with short sit
4:00 - 4:10	Explain loving kindness Get group to decide on a moment of love/kindness Explain about strong emotions, grounding (eg feeling feet on the floor), ignoring my voice, returning to breath if feel overwhelmed.
4:10 - 4:30	Loving Kindness Guided Practice
4:30 - 4:45	Enquiry : Loving Kindness
4:50- 5:00	Proposing home practice choices - one mindful thing a day. Fill in HAT Qu

SESSION 6

Time	Activity	Facilitator
3:00 - 3:10	Welcome Outline the session remind mobiles off Any questions? fill in Well-Being Qu	Sonya
3:10 - 3:30	Sitting Practice (introduce use of bells as object of mindfulness and reminder to check your mindfulness)	Sonya
3:30 - 3:50	Enquiry re: sitting Enquiry: home Practice (especially breathing spaces) Compassion, commitment - where are you now?	Sonya
3:50 - 4:00	Toilet break	
4:00 - 4:05	Settle with short sit	Paul
4:05 - 4:40	Group exercise about how you deal with periods of difficulty/stress/ill health. Responding rather than reacting how does our practice of mindfulness fit in? How could you use mindfulness?	
4:40 - 4:50	Coping Space & Wild Geese Poem	Paul
4:50- 5:00	Proposing home practice choices - one mindful thing a day. Try out coping space. Fill in HAT Qu	Paul

SESSION 7 - How can I best take care of myself and my diabetes?

Time	Activity	Facilitator
3:00 - 3:10	Welcome Outline the session remind mobiles off Any questions? fill in Well-Being Qu	Sonya
3:10 - 3:30	Walking meditation	Sonya
3:30 - 3:50	Enquiry re: walking Enquiry: home Practice (especially coping spaces)	Sonya Paul
3:50 - 4:00	Toilet break	
4:00 - 4:05	Settle with short sit	Sonya
4:05 - 4:30	Discussion – As a group. What helps me feel alive & present? What drains me? What do I need to do which hasn't come easily (apply to diabetes self-care)?	Paul
4:30 - 4:40	Enquiry - Discussion Listing aspects of life with diabetes which they react to or try to avoid (flip chart)	Paul
4:40 - 4:50	Coping Space Tailored to turn towards the diabetes difficulties. How am I right now? What do I need to do? What's getting in the way? How can I overcome it? Wise mind – best course of action might be no action	Paul
4:50- 5:00	Proposing home practice choices - one mindful thing a day. Try out new coping space. Fill in HAT Qu	Paul

SESSION 8 - Ending

Time	Activity	Facilitator
3:00 - 3:30	Welcome Outline the session remind mobiles off Any questions? fill in Full Questionnaire Pack	Sonya
3:30 - 3:45	Mindful Eating (Strawberries)	Sonya
3:45 - 4:00	Enquiry re: Mindful eating (contrast with first session)	Sonya
4:00 - 4:05	Toilet break	
4:05 - 4:10	Settle with short sit (include Enough poem)	Paul
4:40 - 4:50	Re-open Envelopes from session 1 Sit & reflect on what you've gained from the course	Sonya
4:10 - 4:30	Discussion & Brainstorm – As a group. Sustaining the practice. Cost, benefit analysis. Form a mindfulness Support group? Follow-up meeting. Give out CD's and practice advice sheet	Both
4:50- 5:00	Goodbyes (until FU grp) Read The Journey poem Proposing home practice choices - one mindful thing a day. Fill in HAT Qu	Paul Sonya

APPENDIX 2

PATIENT INFORMATION SHEET

&

CONSENT FORM

Investigators:

Dr. Martin Press (Consultant endocrinologist)
Dr. Sonya Frearson (Trainee Clinical Psychologist)
Dr. Paul Chadwick
(Clinical & Health Psychologist, Royal Free Hospital)

PATIENT INFORMATION SHEET

v.2

17.08.05

Evaluation of a Mindfulness-Based Stress Reduction Group for People Living with Diabetes

Evaluation of a Mindfulness Meditation Group for People Living with Diabetes

We are inviting you to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What the Group is About

The Diabetes Service at the Royal Free Hospital will be starting a new type of group for people with diabetes. The group will be offered as a pilot to find out whether people find it useful and whether it helps them. You can choose to opt in to the group in addition to any other services you receive.

Mindfulness-based therapy approaches have been used to bring symptom relief and meaning to the lives of people with a wide range of physical health problems in the United States. In the UK, Mindfulness-based cognitive therapy has been shown to reduce the chance of getting depressed again for people with recurrent depression. The research already done shows that when practiced regularly meditation can help you to overcome a number of problems:

- Worry.
- Unwanted behaviours (overeating, drug or alcohol use).

- Depression and anxiety.
- Guilt and shame.
- Physical pain and disability.
- Sleep problems.

But meditation is not just about the relief of suffering. More importantly it is a way of understanding ourselves and a means to live more happily within one's own skin.

Why are we doing the study?

This group will be the first time this type of approach has been specifically applied to diabetes in the UK. For this reason we will be carefully evaluating how the participants get on and what their opinion of the group was as a research study.

Why have I been chosen?

We are hoping that a group of 20 people will take part in the study. We are asking people with diabetes (either type 1 or 2) who use the diabetes service at the Royal Free Hospital if they would like to take part.

As this type of therapy is quite new to the NHS and all the effects of it are not yet known we will be adopting a cautious approach to choosing participants. We will take care to check that this type of therapy will be safe and helpful for you at this time in your life. This will involve you filling in questionnaires and if necessary having an assessment with one of us. If we do not think that it would be advisable for you to come to the group at the moment we will discuss this with you and we will let you know about other services which may better meet your needs. However, we expect that the mindfulness group will be suitable for most people who would like to try it.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

There will be eight weekly two-hour mindfulness meditation group sessions which will be experiential and discussion based. The group will meet at the

Royal Free Hospital. The sessions will be lead by Sonya Frearson and Paul Chadwick. Sonya is a Trainee Clinical Psychologist who has had her own meditation practice for ten years and who has been training as a meditation instructor for two years. She has previously run mindfulness meditation groups for NHS patients and staff. Paul Chadwick is a Chartered Clinical & Health Psychologist, he has had his own mediation practice for two years and routinely runs therapeutic groups as part of his clinical work. He has been using mindfulness meditation with individual patients who are living with diabetes and has been listening to their experiences of using it.

In order to evaluate the therapy the ninth meeting will be a discussion and feedback session about your experiences of the group and of using mindfulness meditation. This session will be conducted by two psychologists who are experienced in working with people with diabetes and who use mindfulness themselves. They will not be the same people who have facilitated the other group sessions. We will be audio-taping this session so that we can analyse the data, however, the group facilitators will not find out who made which comments in the feedback group.

The other way in which we will be studying how the therapy worked will be to ask you to fill in some questionnaires before the group begins, at the first and last group and at the follow-up meeting. We will analyse whether there were any changes in your reports of your attitudes, mindfulness, well-being, quality of life and ability to care for yourself while you took part in the group. The questionnaires will take around 20 minutes to fill in and we will make time for this at the beginning of the sessions. We would also like to ask your permission to include your routine health check information (for example your blood results) in our analysis. You will not need to have any extra-medical investigations as part of our research.

What do I have to do?

We believe that you will get more benefit from the intervention if you attend most or all of the group sessions (two hours a week for nine weeks and a follow-up meeting) and you will need to practice the meditation exercises during the week (which exercise you try and for how long is up to you, anything from five minutes to an hour a day). We would appreciate it if you would think carefully about whether you will be able to make this kind of commitment at the moment. If you think you can't you may be able to make use of other services which we can advise you about. We also hope to offer more mindfulness groups in the future but that will depend on what the members of this group tell us about their experiences of it.

As well as coming to the group you should continue to do whatever your other healthcare professionals have advised you to do to manage your diabetes and any other health problems.

Are there any side effects or risks associated with the treatment?

The premise of mindfulness-based approaches is to allow you to be able to be present and accepting of whatever you are experiencing whether this is pleasant or unpleasant. As with any psychological treatment it is possible that you may feel worse before you feel better. As we've mentioned this is a new treatment and it is possible that there are some unknown side-effects or risks.

Some meditators have reported unusual sensory or perceptual experiences (like feeling unlike themselves, feeling very small, seeing vivid images) such experiences are very rare and are temporary. If you do experience anything unusual or distressing while practising mindfulness meditation please speak to the facilitators about it so that they can help you to make sense of your experience. Between sessions you can leave messages for them to call you back on: 0207 530 6800 (Dr Chadwick's Secretary).

If anything changes about your health which concerns you, you should contact your usual doctor.

What are the possible disadvantages of taking part?

You will need to weigh up whether the potential benefits of the treatment will make it worthwhile for you to spend time participating in the treatment, filling in the questionnaires and giving feedback on your experiences. You should bear in mind that if you decide to use the meditation exercises everyday it may involve some adjustment to your daily routine in order to make time for this (even if you only practice them for five minutes).

What are the possible benefits of taking part?

One of the aims of our study is to find out more about the benefits (and difficulties) of using mindfulness for people with diabetes. We hope that the treatment will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future patients with diabetes better.

The treatment is likely to make you feel relaxed and could help you improve your ability to concentrate. It may also bring benefits such as less worry and anxiety, more enjoyment of everyday life, better sleep, less pain and a sense of well-being. You will also have the opportunity to meet other people with diabetes and to spend time discussing your experiences with them.

What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the group facilitators will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw they will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

Also, on receiving new information the group facilitators might consider it to be in your best interests to withdraw you from the study. They will explain the reasons and arrange for your care to continue.

What happens when the research study stops?

After the nine sessions of the group there will be a follow-up session. If you have found mindfulness beneficial then we will encourage you to continue to use the practices you have learnt in the group after this.

What if something goes wrong?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you. University College London (UCL) is sponsoring this study and providing indemnity in the event that you are harmed as a result of taking part in the study. Any claims for clinical negligent harm can be made through the NHS Clinical Negligence Scheme for Trusts as per Trust protocol.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it.

As the study is additional to your usual care and you will in effect refer yourself to the group, we will not be informing your GP of your participation unless you specifically ask us to do so.

What will happen to the results of the research study?

The results of the study will be written up by Dr Frearson for her Doctor of Clinical Psychology thesis. We will produce a summary of the main findings to send to you. We also hope to present the research at conferences and to submit it to peer reviewed journals for publications. You will not be identified in any report or publication we make from the study.

Who is organising and funding the research?

The diabetes service at the Royal Free Hospital will pay for including you in this study.

Who has reviewed the study?

The Research Ethics Committee at the Royal Free Hospital has reviewed the study.

Contact for Further Information

Dr Paul Chadwick (Clinical & Health Psychologist),

Tel:

Thank-you for reading this information sheet. Please keep your copy as well as a copy of the consent form. If you decide to take part then we look forward to working with you.

Investigators:

**Dr. Martin Press (Consultant
endocrinologist)
Dr. Sonya Frearson (Trainee Clinical
Psychologist)
Dr. Paul Chadwick
Clinical & Health Psychologist, Royal Free**

**Clinical Health Psychology
Department**

v.1 17.08.02

**Evaluation of a Mindfulness-Based Stress Reduction Group for People Living with
Diabetes**

CONSENT FORM

Please initial

box

1. I confirm that I have read and understand the information
sheet for the above study and have had the opportunity to ask
the researchers questions. ☐
2. I understand that my participation is entirely voluntary and that
I am free to withdraw at any time, without giving any reason and without
my medical care or legal rights being affected. (Therefore, if I no longer
wanted to take part in the research but still wanted to come to the group
there would be no problem). ☐
3. I understand that the researchers (and individuals from research regulatory
authorities) will look at my medical notes for details of my routine health checks
and blood tests. I give permission for these individuals to access my medical
records for this purpose. ☐
4. I understand that the 9th group session will be an opportunity for the group
members to give feedback on their experiences to independent facilitators.
This session will be audio-taped and I understand that any comments I make
will not be identified to the researchers as coming from me. I consent to be
audio-taped during this session. ☐
5. I agree to take part in the above study. ☐

Signed:..... Date:.....

NAME IN BLOCK LETTERS:.....

Please keep one copy of this form

Signed Researcher:..... Name:.....

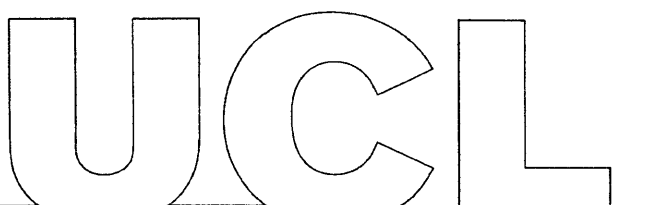
Date:.....

One copy to be kept by researcher and one, one copy to go in hospital notes.

APPENDIX 3
ETHICS PERMISSION LETTERS

UCL BIOMEDICINE RESEARCH & DEVELOPMENT UNIT

Dr Martin Press
Consultant Endocrinologist
Department of Diabetes, Metabolism and Endocrinology
Royal Free Hospital



16th August 2005

Dear Dr Press

Study Title: Evaluation of a Mindfulness-Based Stress Reduction (MBSR) Group for People Living with Diabetes

Funder: In-house funds

Chief Investigator: Dr Martin Press

Principal Investigator: Dr Sonya J. Frearson

UCL Academic Supervisor: Dr Susan Michie

Sponsor's Project ID Number: BRD/05/111

I confirm that University College London (UCL) will act as Research Governance Sponsor for the above study.

As Sponsor we undertake to ensure that the above study is conducted in accordance with the Research Governance Framework (Second Edition, April 2005) and confirm that arrangements and agreements are in place for the initiation, management, monitoring and financing of this study.

As Chief Investigator for the study, you must ensure that the study will not commence until all applicable approvals have been obtained and a written sponsor agreement, with allocation of responsibilities and delegation of duties, is issued and signed by all parties involved in the study.

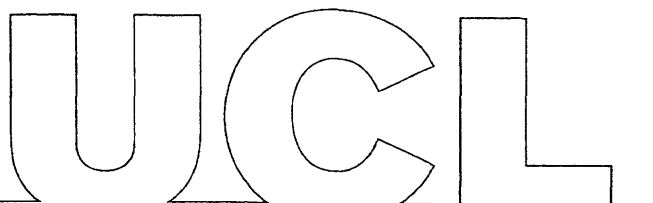
Yours sincerely

Research Governance Co-ordinator
UCL Biomedicine R&D Unit

cc: Dr Sonya Frearson, Sub-department of Clinical Health Psychology, UCL
Dr Susan Machie, UCL Academic Supervisor, Sub-department of Clinical Health Psychology
Dr Paul Chadwick, Project Supervisor, Cancer Research UK Health Behaviour Unit, UCL
QA Manager, UCL Biomedicine R&D Unit

UCL BIOMEDICINE RESEARCH & DEVELOPMENT UNIT

Dr Martin Press
Consultant Endocrinologist
Department of Diabetes, Metabolism and Endocrinology
Royal Free Hospital



16th August 2005

Dear Dr Press

Study Title: Evaluation of a Mindfulness-Based Stress Reduction (MBSR) Group for People Living with Diabetes

Funder: In-house funds

Chief Investigator: Dr Martin Press

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UCL Academic Supervisor: Dr Susan Michie

Sponsor's Project ID Number: BRD/05/111

Re: UCL non-negligent harm insurance.

Thank you for registering the above study with the UCL Biomedicine R&D Unit.

I am pleased to inform you that the above referenced study, as detailed in your UCL Insurance Registration Form of 18th July 2005, has been included on the register for UCL's insurer's 'Clinical Trials Policy', which provides insurance for non-negligent harm. This letter supersedes the insurance confirmation letter dated 4th August 2005.

Feel free to contact me if you have any queries concerning the cover.

Yours sincerely

Research Governance Co-ordinator
UCL Biomedicine R&D Unit

cc: Dr Sonya Frearson, Sub-department of Clinical Health Psychology, UCL
Dr Susan Machie, UCL Academic Supervisor, Sub-department of Clinical Health Psychology
Dr Paul Chadwick, Project Supervisor, Cancer Research UK Health Behaviour Unit, UCL
QA Manager, UCL Biomedicine R&D Unit

Royal Free Hampstead



NHS Trust

Directorate of Human Resources
Royal Free Hospital

8 April 2005

PRIVATE & CONFIDENTIAL

Dr Sonya Frearson
Sub-Department of Clinical Health Psychology
University College London

Director of Human Resources: Nigel Turner

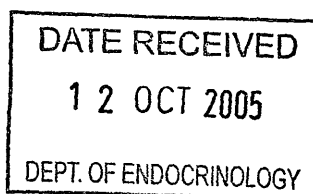
Dear Sonya,

HONORARY CONTRACT





Royal Free Hospital & Medical School
Local Research Ethics Committee



26 September 2005

Dr Martin Press
Consultant Endocrinologist
Department Diabetes, Metabolism and Endocrinology, Royal Free Hospital

Dear Dr Press

Full title of study: Evaluation of a Mindfulness-Based Stress Reduction (MBSR) Group for People Living with Diabetes
REC reference number: 05/Q0501/162

The Research Ethics Committee reviewed the above application at the meeting held on 21 September 2005.

Ethical opinion

The applicant attended

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation.

Ethical review of research sites

The favourable opinion applies to the research sites listed on the attached form.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Application	4.1	31 August 2005
Investigator CV		28 June 2005
Protocol		01 December 2004
Summary/Synopsis		
Letter from Sponsor		16 August 2005
Interview Schedules/Topic Guides		

Questionnaire		
Questionnaire		
Advertisement		
GP/Consultant Information Sheets		
Participant Information Sheet	version 2	17 August 2005
Participant Consent Form	version 1	17 August 2005
Statement of Indemnity		16 August 2005
Letter from Statistician		
Letter from Funder		21 March 2005
Referees; or other scientific critique report		08 December 2004
(Student) Dr Frearson and (Supervisor) Dr Chadwick C.V.s		
Other		

Research governance approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final research governance approval from the R&D Department for the relevant NHS care organisation.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

05/Q0501/162	Please quote this number on all correspondence
--------------	--

With the Committee's best wishes for the success of this project

Yours sincerely

Chair

Email:

Enclosures:

List of names and professions of members who were present at the meeting and those who submitted written comments
Standard approval conditions [SL-AC1 for CTIMPs, SL-AC2 for other studies]
Site approval form (SF1)

Copy to:

[R&D Department for NHS care organisation at lead site]

Royal Free Hospital & Medical School Local Research Ethics Committee

Attendance at Committee meeting on 21 September 2005

Committee Members:

Name	Profession	Present?	Notes
	Chairman	No	
	Lay Member (Vice Chair)	Yes	
	Head of Pharmaceutical Services	Yes	
	Surgery	No	
	Nuclear Medicine	Yes	
	Clinical Trial Pharmacist	Yes	
	Professor O & G, RFUCMS, Hampstead Campus	Yes	
	Hepatology	No	
	Public Health & Primary Care - Statistician	Yes	
	CONSULTANT NEUROLOGIST	Yes	
	Nurse	No	
	Dispensing Pharmacist	No	
	Paediatrician	Yes	
	Journalist	No	
	Lay Member	Yes	

Also in attendance:

Name	Position (or reason for attending)
------	------------------------------------

Royal Free Hospital & Medical School Local Research Ethics Committee

LIST OF SITES WITH A FAVOURABLE ETHICAL OPINION

For all studies requiring site-specific assessment, this form is issued by the main REC to the Chief Investigator and sponsor with the favourable opinion letter and following subsequent notifications from site assessors. For issue 2 onwards, all sites with a favourable opinion are listed, adding the new sites approved.

REC reference number:	05/Q0501/162	Issue number:	1	Date of issue:	26 September 2005
Chief Investigator:	Dr Martin Press				
Full title of study:	Evaluation of a Mindfulness-Based Stress Reduction (MBSR) Group for People Living with Diabetes				
<p><i>This study was given a favourable ethical opinion by Royal Free Hospital & Medical School Local Research Ethics Committee on 21 September 2005. The favourable opinion is extended to each of the sites listed below. The research may commence at each NHS site when management approval from the relevant NHS care organisation has been confirmed.</i></p>					
<i>Principal Investigator</i>	<i>Post</i>	<i>Research site</i>	<i>Site assessor</i>	<i>Date of favourable opinion for this site</i>	<i>Notes ⁽¹⁾</i>
Dr Martin Press	Consultant Physician in Diabetes, Endocrinology and General Medicine	Royal Free Hospitals NHS Trust	Royal Free Hospital & Medical School Local Research Ethics Committee	26/09/2005	
<p>Approved by the Chair on behalf of the REC:</p> <p align="center">..... (Signature of Chair/Administrator)</p> <p>(delete as applicable)</p> <p>..... (Name)</p>					

-
- (1) *The notes column may be used by the main REC to record the early closure or withdrawal of a site (where notified by the Chief Investigator or sponsor), the suspension of termination of the favourable opinion for an individual site, or any other relevant development. The date should be recorded.*

Royal Free Hampstead NHS Trust

Please reply

R&D Office
Royal Free Hampstead NHS Trust

Telephone:
Fax:
E-mail:

Dr Martin Press
Department of Endocrinology & Diabetes
Royal Free Hampstead NHS Trust

Friday, October 21, 2005

Dear Dr Press

**ID: 7151 Evaluation of a Mindfulness-Based Stress Reduction (MBSR) Group
for people living with diabetes.**

ROYAL FREE TRUST HAMPSTEAD NHS TRUST APPROVAL FOR R&D PROJECTS

I am pleased to inform you that following our letter of conditional trust approval and receipt of confirmation of ethics approval your project now has full approval. This letter ensures that you and the researchers working with you, who hold substantive or honorary trust contracts, are indemnified by the trust, under department of health HSG (96) 48, for non commercial research only. This means you can now proceed with your project.

The term of approval is co-terminous with the term of ethics approval, unless the R&D office has reason to withdraw approval at an earlier date. If you wish to continue the research project beyond this date, a written request must be made to the ethics committee for an extension. A copy of this extension letter will also be required by the R&D office. Trust approval may be withdrawn if ethics approval is withdrawn or in cases of research fraud or misconduct.

In addition to ensuring your study complies with good clinical research practice as outlined in the ICH GCP guidelines we require the following:

Patient contact - only trained researchers holding a trust contract (honorary or full) are allowed to make contact with patients.

Informed Consent – Only the lead researcher or other trained researcher should obtain signed consent and in accordance with the Ethics Committee requirements. The original signed consent form should be kept on file and informed consent will be monitored by the trust at intervals when you will be required to provide the relevant documentation.

Confidentiality - All those involved in the study appreciate the importance of maintaining confidentiality and that they comply with the Data Protection Act 1988.

Amendments – The R&D office must be kept informed of any changes to the project for example regarding patient recruitment, funding, personnel changes or your project status. If changes are made to the protocol they will need to be considered by the Ethics Committee.

Deviations from protocol - the R&D office must be kept informed of any significant deviations from the protocol.

Adverse events - the R&D office must be notified immediately of any adverse events.

Research misconduct and fraud - please note that all research will be monitored to detect research misconduct and fraud. Appropriate action will be taken where this is detected.

Progress report – A progress report will need to be completed annually.

Publications – Any publication resulting from your project must be reported to the R&D office. This is vital in ensuring the quality and output of research across the trust.

Lay executive summary - on completion of your research project you must send the R&D office a one-paragraph summary of your project, written in simple lay language, understandable to the average 12-year old. These summaries are used to inform the public of research activities and findings and will be placed on both the Trust intranet and on the Trust internet, which is accessible to the public.

NHS Funding - If the project uses any trust resources any publication must include the following statement. 'This work was undertaken by [investigator's name] with the Royal Free Hampstead NHS Trust who received [funding or a proportion of its funding] from the NHS Executive; the views expressed in this publication are those of the author(s) and not necessarily those of the Trust or NHS Executive.'

Data Protection - This approval is subject to your consent for information about your project to be included in NHS project registration/ management databases and, where appropriate, the National Research Register and the UCL Clinical Research Network register.

Yours sincerely


Dr Gerarda Gamelkoorn
Director of Clinical Research

APPENDIX 4
QUESTIONNAIRES USED

Clinical Health Psychology Department, Royal Free Hospital

Mindfulness-Based Stress Reduction for People Living with Diabetes

SELF-REPORT QUESTIONNAIRES

CONFIDENTIAL

TODAY'S DATE (dd/mm/yy): ____ / ____ / ____

PARTICIPANT ID NUMBER:

Investigators:
Dr. Martin Press and Dr. Sonya Frearson

Dr. Paul Chadwick
Clinical & Health Psychologist, Royal Free Hospital

CONFIDENTIAL (when completed)

ABOUT YOU.....

The following questions are about you. Please answer the questions as best you can, by ticking the relevant box. The information will help us to describe the results of our research, and compare results between different people.

1. What is the highest level of education you have completed?

GCSEs/NVQs	<input type="checkbox"/>
A Levels/Diploma/HND	<input type="checkbox"/>
Degree	<input type="checkbox"/>
Postgraduate Degree	<input type="checkbox"/>
Vocational (please specify)	<input type="checkbox"/>
Other (please specify)	<input type="checkbox"/>

2. Are you:

Male	<input type="checkbox"/>
Female	<input type="checkbox"/>

3. Are you currently:

Single	<input type="checkbox"/>
Married/In a partnership	<input type="checkbox"/>
Separated/Divorced	<input type="checkbox"/>
Widowed	<input type="checkbox"/>

4. During the past 12 months, what best describes your main activity?
Were you mainly...?

Working at a job/Self-employed	<input type="checkbox"/>
Looking for work	<input type="checkbox"/>
Unemployed due to disability	<input type="checkbox"/>
Raising children/Keeping house	<input type="checkbox"/>
Full-time carer	<input type="checkbox"/>
A student	<input type="checkbox"/>
Retired	<input type="checkbox"/>
Other (please specify)	<input type="checkbox"/>

5. Which of the following categories includes your total household income (before taxes) in the last tax year?

Under £10,000	<input type="checkbox"/>
£10,000 - £29,999	<input type="checkbox"/>
£30,000 - £49,999	<input type="checkbox"/>
£50,000 - £69,999	<input type="checkbox"/>
£70,000 and above	<input type="checkbox"/>

6. What is your ethnic background? Please specify (or leave blank if you do not wish to disclose).....

-
7. Have you ever tried any of these activities?

Meditation	<input type="checkbox"/>
Tai Chi	<input type="checkbox"/>
Yoga	<input type="checkbox"/>

Thank you for this information.

INSTRUCTIONS

The remainder of this questionnaire contains a set of questions, which ask about various aspects of your health. When answering these questions please think about your health and your ability to do things on a **day-to-day basis, in recent weeks**. Please focus your answers on your overall abilities, disabilities and how you felt.

You may feel that some of these questions do not apply to you, but it is important that we ask the same questions of everyone. Also, a few questions are similar; please excuse the apparent overlap and answer each question independently.

Please read each question and consider your answers carefully. For each question, please select one answer that best describes your level of health.

All the information that you provide is confidential. There are no right or wrong answers; what we want is your opinion about your abilities and feelings.

PRIME-MD PHQ

1. During the last 4 weeks, how much have you been bothered by any of the following problems? Please answer every question to the best of your ability unless you are requested to skip over a question.

	Not bothered	Bothered a little	Bothered a lot
a. Stomach pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Back pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Pain in your arms, legs, or joints (knees, hips, etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Menstrual cramps or other problems with your periods	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Pain or problems during sexual intercourse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Headaches	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Chest pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Dizziness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Fainting spells	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. Feeling your heart pound or race	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k. Shortness of breath	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l. Constipation, loose bowels or diarrhoea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m. Nausea, gas or indigestion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Not at all	Several days	More than half the days	Nearly every day
a. Little interest or pleasure in doing things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Feeling down, depressed, or hopeless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Trouble falling or staying asleep, or sleeping too much	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Feeling tired or having little energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Poor appetite or overeating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Trouble concentrating on things, such as reading the newspaper or watching television	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Thoughts that you would be better off dead or of hurting yourself in some way	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. Questions about anxiety	No	Yes	
a. In the <u>last 4 weeks</u> , have you had an anxiety attack — suddenly feeling fear or panic?	<input type="checkbox"/>	<input type="checkbox"/>	
If you answered 'NO' go to question 5.			
b. Has this ever happened before?	<input type="checkbox"/>	<input type="checkbox"/>	
c. Do some of these attacks come <u>suddenly out of the blue</u> — that is, in situations where you don't expect to be nervous or uncomfortable?	<input type="checkbox"/>	<input type="checkbox"/>	
d. Do these attacks bother you a lot or are you worried about having another attack?	<input type="checkbox"/>	<input type="checkbox"/>	
4. Think about your last bad anxiety attack.	No	Yes	
a. Were you short of breath?	<input type="checkbox"/>	<input type="checkbox"/>	
b. Did your heart race, pound, or skip?	<input type="checkbox"/>	<input type="checkbox"/>	
c. Did you have chest pain or pressure?	<input type="checkbox"/>	<input type="checkbox"/>	
d. Did you sweat?	<input type="checkbox"/>	<input type="checkbox"/>	
e. Did you feel as if you were choking?	<input type="checkbox"/>	<input type="checkbox"/>	
f. Did you have hot flashes or chills?	<input type="checkbox"/>	<input type="checkbox"/>	
g. Did you have nausea or an upset stomach, or the feeling that you were going to have diarrhoea?	<input type="checkbox"/>	<input type="checkbox"/>	
h. Did you feel dizzy, unsteady, or faint?	<input type="checkbox"/>	<input type="checkbox"/>	
i. Did you have tingling or numbness in parts of your body?	<input type="checkbox"/>	<input type="checkbox"/>	
j. Did you tremble or shake?	<input type="checkbox"/>	<input type="checkbox"/>	
k. Were you afraid you were dying?	<input type="checkbox"/>	<input type="checkbox"/>	
5. Over the last 4 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days
a. Feeling nervous, anxious, on edge, or worrying a lot about different things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If you answered "NOT AT ALL", go to question 6.			
b. Feeling restless so that it is hard to sit still	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Getting tired very easily	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Muscle tension, aches, or soreness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Trouble falling asleep or staying asleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Trouble concentrating on things, such as reading a book or watching TV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Becoming easily annoyed or irritable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. Questions about eating	No	Yes
a. Do you often feel that you can't control <u>what</u> or <u>how much</u> you eat?	<input type="checkbox"/>	<input type="checkbox"/>
b. Do you often eat, <u>within any 2-hour period</u> , what most people would regard as an unusually <u>large</u> amount of food?	<input type="checkbox"/>	<input type="checkbox"/>

If you answered 'NO' to either a or b go to question 9.

c. Has this been as often, on average, as twice a week for the last 3 months?	<input type="checkbox"/>	<input type="checkbox"/>
7. In the last 3 months have you <u>often</u> done any of the following in order to avoid gaining weight?	No	Yes
a. Made yourself vomit?	<input type="checkbox"/>	<input type="checkbox"/>
b. Took more than twice the recommended dose of laxatives?	<input type="checkbox"/>	<input type="checkbox"/>
c. Fasted — not eaten anything at all for at least 24 hours?	<input type="checkbox"/>	<input type="checkbox"/>
d. Exercised for more than an hour specifically to avoid gaining weight after binge eating?	<input type="checkbox"/>	<input type="checkbox"/>
e. Omit your insulin injections?	<input type="checkbox"/>	<input type="checkbox"/>
8. If you answered 'YES' to any of these ways of avoiding gaining weight, were any as often, on average, as twice a week?	No	Yes
	<input type="checkbox"/>	<input type="checkbox"/>
9. Do you ever drink alcohol (including beer or wine)?	No	Yes
	<input type="checkbox"/>	<input type="checkbox"/>

If you answered 'NO' go to question 11.

10. Have any of the following happened to you <u>more than once in the last 6 months</u>?	No	Yes
a. You drank alcohol even though a doctor suggested that you stop drinking because of a problem with your health	<input type="checkbox"/>	<input type="checkbox"/>
b. You drank alcohol, were high from alcohol, or hung over while you were working, going to school, or taking care of children or other responsibilities	<input type="checkbox"/>	<input type="checkbox"/>
c. You missed or were late for work, school, or other activities because you were drinking or hung over	<input type="checkbox"/>	<input type="checkbox"/>
d. You had a problem getting along with other people while you were drinking	<input type="checkbox"/>	<input type="checkbox"/>
e. You drove a car after having several drinks or after drinking too much	<input type="checkbox"/>	<input type="checkbox"/>

11. If you said yes to any problems on this questionnaire, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult
at all

Somewhat
difficult

Very
difficult

Extremely
difficult

☐

☐

☐

☐

12. In the last 4 weeks, how much have you been bothered by any of the following problems?

Not
bothered

Bothered
a little

Bothered
a lot

- a. Worrying about your health

☐

☐

☐

- b. Your weight or how you look

☐

☐

☐

- c. Little or no sexual desire or pleasure during sex

☐

☐

☐

- d. Difficulties with husband/wife, partner/lover or boyfriend/girlfriend

☐

☐

☐

- e. The stress of taking care of children, parents, or other family members

☐

☐

☐

- f. Stress at work, outside of the home or at school

☐

☐

☐

- g. Financial problems or worries

☐

☐

☐

- h. Having no one to turn to when you have a problem

☐

☐

☐

- i. Something bad that happened recently

☐

☐

☐

- j. Thinking or dreaming about something terrible that happened to you in the past - like your house being destroyed, a severe accident, being hit or assaulted, or being forced to commit a sexual act

☐

☐

☐

13. In the last year, have you been hit, slapped, kicked or otherwise physically hurt by someone, or has anyone forced you to have an unwanted sexual act?

No

Yes

☐

☐

- 14.

What is the most stressful thing in your life right now?

15. Are you taking any medicine for anxiety, depression or stress?

No

Yes

☐

☐

If yes, What is the name of the medicine you are taking?

HADS

16.	I feel tense or "wound-up"	Most of the time	A lot of the time	Occasionally	Not at all
17.	I feel as if I am slowed down	<input type="checkbox"/> Nearly all the time	<input type="checkbox"/> Very often	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Not at all
18.	I still enjoy the things I used to enjoy	<input type="checkbox"/> Definitely as much	<input type="checkbox"/> Not quite so much	<input type="checkbox"/> Only a little	<input type="checkbox"/> Hardly at all
19.	I get a sort of frightened feeling like "butterflies" in the stomach	<input type="checkbox"/> Not at all	<input type="checkbox"/> Occasionally	<input type="checkbox"/> Quite Often	<input type="checkbox"/> Very often
20.	I get a sort of frightened feeling as if something awful is about to happen	<input type="checkbox"/> Very definitely and quite badly	<input type="checkbox"/> Yes but not too badly	<input type="checkbox"/> A little but it doesn't worry me	<input type="checkbox"/> Not at all
21.	I have lost interest in my appearance	<input type="checkbox"/> Definitely	<input type="checkbox"/> I don't take as much care as I should	<input type="checkbox"/> I may not take quite as much care	<input type="checkbox"/> I take just as much care as ever
22.	I can laugh and see the funny side of things	<input type="checkbox"/> As much as I always could	<input type="checkbox"/> Not quite so much now	<input type="checkbox"/> Definitely not quite so much now	<input type="checkbox"/> Not at all
23.	I feel restless as if I have to be on the move	<input type="checkbox"/> Very much indeed	<input type="checkbox"/> Quite a lot	<input type="checkbox"/> Not very much	<input type="checkbox"/> Not at all
24.	Worrying thoughts go through my mind	<input type="checkbox"/> A great deal of the time	<input type="checkbox"/> A lot of the time	<input type="checkbox"/> From time to time but not too often	<input type="checkbox"/> Only occasionally
25.	I look forward with enjoyment to things	<input type="checkbox"/> As much as I ever did	<input type="checkbox"/> Rather less than I used to	<input type="checkbox"/> Definitely less than I used to	<input type="checkbox"/> Hardly at all
26.	I feel cheerful	<input type="checkbox"/> Not at all	<input type="checkbox"/> Not often	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Most of the time
27.	I get sudden feelings of panic	<input type="checkbox"/> Very often indeed	<input type="checkbox"/> Quite often	<input type="checkbox"/> Not very often	<input type="checkbox"/> Not at all
28.	I can sit at ease and feel relaxed	<input type="checkbox"/> Definitely	<input type="checkbox"/> Usually	<input type="checkbox"/> Not often	<input type="checkbox"/> Not at all
29.	I can enjoy a good book or radio or TV programme	<input type="checkbox"/> Often	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Not often	<input type="checkbox"/> Seldom
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

PAID

Which of the following diabetes issues are currently a problem for you?

Circle the number that gives the best answer for you. Please provide an answer for each question.

	Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
Not having clear and concrete goals for your diabetes care?	0	1	2	3	4
Feeling discouraged with your diabetes treatment plan?	0	1	2	3	4
Feeling scared when you think about living with diabetes?	0	1	2	3	4
Uncomfortable social situations related to your diabetes care? (e.g. people telling you what to eat?)	0	1	2	3	4
Feelings of deprivation regarding food and meals?	0	1	2	3	4
Feeling depressed when you think about living with diabetes?	0	1	2	3	4
Not knowing if your mood or feelings are related to your diabetes?	0	1	2	3	4
Feeling overwhelmed by your diabetes?	0	1	2	3	4
Worrying about low blood sugar reactions?	0	1	2	3	4
Feeling angry when you think about living with diabetes?	0	1	2	3	4
Feeling constantly concerned about food and eating?	0	1	2	3	4
Worrying about the future and the possibility of serious complications?	0	1	2	3	4

	Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
Feelings of guilt or anxiety when you get off track with your diabetes management?	0	1	2	3	4
Not "accepting" your diabetes?	0	1	2	3	4
Feeling unsatisfied with your diabetes physician?	0	1	2	3	4
Feeling that diabetes is taking up too much of your mental and physical energy every day?	0	1	2	3	4
Feeling alone with your diabetes?	0	1	2	3	4
Feeling that your friends and family are not supportive of your management efforts?	0	1	2	3	4
Coping with the complications of diabetes?	0	1	2	3	4
Feeling "burned out" by the constant effort needed to manage diabetes?	0	1	2	3	4

Thank-you!

The Summary of Diabetes Self-Care Activities

The questions below ask you about your diabetes self-care activities during the PAST SEVEN DAYS. If you were sick during the past seven days, please think back to the last seven days that you were not sick.

Diet

How many of the last SEVEN days have you followed a healthful eating plan?

0 1 2 3 4 5 6 7

On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you space carbohydrates evenly through the day?

0 1 2 3 4 5 6 7

Exercise

On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking).

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?

0 1 2 3 4 5 6 7

Blood Sugar Testing

On how many of the last SEVEN DAYS did you test your blood sugar?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?

0 1 2 3 4 5 6 7

Medications

On how many of the last SEVEN DAYS did you take your recommended diabetes medication (for example insulin injections or diabetes pills)?

0 1 2 3 4 5 6 7

Foot Care

On how many of the last SEVEN DAYS did you check your feet?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you inspect the inside of your shoes?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you wash your feet?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you soak your feet?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you dry between your toes after washing?

0 1 2 3 4 5 6 7

Smoking

Have you smoked a cigarette – even one puff – during the past SEVEN DAYS?

- 0. No
- 1. Yes. If yes, how many cigarettes did you smoke on an average day?
Number of cigarettes _____

When did you last smoke a cigarette?

- ☐ More than two years ago, or never smoked
- ☐ One to two years ago
- ☐ Four to twelve months ago
- ☐ One to three months ago
- ☐ Within the last month
- ☐ Today

At your last doctor's visit, did anyone ask about your smoking status?

- 0. No
- 1. Yes

If you smoke, at your last doctor's visit, did anyone counsel you about stopping smoking or offer to refer you to a stop-smoking program?

- 0. No
- 1. Yes
- 2. Do not smoke

Self-Care Recommendations

1A. Which of the following has your health care team (doctor, nurse, dietician, or diabetes educator) advised you to do?

Please tick all that apply:

- ☐ a. Follow a low-fat eating plan
- ☐ b. Follow a complex carbohydrate diet
- ☐ c. Reduce the number of calories you eat to lose weight
- ☐ d. Eat lots of food high in dietary fibre
- ☐ e. Eat lots (at least 5 servings per day) of fruits and vegetables
- ☐ f. Eat very few sweets (for example, desserts, non-diet soft drinks, chocolate bars)
- ☐ g. Other (please specify) _____
- ☐ h. I have not been given any advice about my diet by my health care team.

2A. Which of the following has your health care team (doctor, nurse, dietician, or diabetes educator) advised you to do?

Please tick all that apply:

- ☐ a. Get low level exercise (such as walking) on a daily basis
- ☐ b. Exercise continuously for at least 20 minutes at least 3 times a week
- ☐ c. Fit exercise into your daily routine (for example, take the stairs instead of the lift, get off at the previous bus stop and walk etc)
- ☐ d. Engage in a specific amount, type, duration and level of exercise.
- ☐ e. Other (please specify) _____
- ☐ f. I have not been given any advice about exercise by my health care team.

3A. Which of the following has your health care team (doctor, nurse, dietician, or diabetes educator) advised you to do?

Please tick all that apply:

- ☐ a. Test your blood sugar using a drop of blood from your finger and a colour chart.
- ☐ b. Test your blood sugar using a machine to read the results
- ☐ c Test your urine for sugar
- ☐ d Other (please specify) _____
- ☐ e I have not been given any advice about testing my blood or urine sugar level by my health care team.

4A Which of the following medications for your diabetes has your doctor prescribed?

Please tick all that apply:

- ☐ a. An insulin injection 1 or 2 times a day
- ☐ b. An insulin injection 3 or more times a day
- ☐ c. Diabetes pills to control my blood sugar level
- ☐ d. Other (please specify) _____
- ☐ e I have not been prescribed either insulin or pills for my diabetes.

MAAS

Participant Number:

Date:

Instructions: Below is a collection of statements about your everyday experience. Using the 1–6 scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what *really reflects* your experience rather than what you think your experience should be. Please treat each item separately from every other item.

1	2	3	4	5	6
Almost Always	Very Frequently	Somewhat Frequently	Somewhat Infrequently	Very Infrequently	Almost Never

I could be experiencing some emotion and not be conscious of it until some time later.	1	2	3	4	5	6
I break or spill things because of carelessness, not paying attention, or thinking of something else.	1	2	3	4	5	6
I find it difficult to stay focused on what's happening in the present.	1	2	3	4	5	6
I tend to walk quickly to get where I'm going without paying attention to what I experience along the way.	1	2	3	4	5	6
I tend not to notice feelings of physical tension or discomfort until they really grab my attention.	1	2	3	4	5	6
I forget a person's name almost as soon as I've been told it for the first time.	1	2	3	4	5	6
It seems I am "running on automatic" without much awareness of what I'm doing.	1	2	3	4	5	6
I rush through activities without being really attentive to them.	1	2	3	4	5	6
I get so focused on the goal I want to achieve that I lose touch with what I'm doing right now to get there.	1	2	3	4	5	6
I do jobs or tasks automatically, without being aware of what I'm doing.	1	2	3	4	5	6
I find myself listening to someone with one ear, doing something else at the same time.	1	2	3	4	5	6

1	2	3	4	5	6
Almost	Very	Somewhat	Somewhat	Very	Almost
Always	Frequently	Frequently	Infrequently	Infrequently	Never

I drive to places on 'automatic pilot' and then wonder why I went there.	1	2	3	4	5	6
I find myself preoccupied with the future or the past.	1	2	3	4	5	6
I find myself doing things without paying attention.	1	2	3	4	5	6
I snack without being aware that I'm eating.	1	2	3	4	5	6

(Self-Compassion Scale)

HOW I TYPICALLY ACT TOWARDS MYSELF IN DIFFICULT TIMES

Please read each statement carefully before answering. To the left of each item, indicate how often you behave in the stated manner, using the following scale:

Almost never					Almost always
1	2	3	4	5	

1. I'm disapproving and judgmental about my own flaws and inadequacies.
2. When I'm feeling down I tend to obsess and fixate on everything that's wrong.
3. When things are going badly for me, I see the difficulties as part of life that everyone goes through.
4. When I think about my inadequacies, it tends to make me feel more separate and cut off from the rest of the world.
5. I try to be loving towards myself when I'm feeling emotional pain.
6. When I fail at something important to me I become consumed by feelings of inadequacy.
7. When I'm down, I remind myself that there are lots of other people in the world feeling like I am.
8. When times are really difficult, I tend to be tough on myself.
9. When something upsets me I try to keep my emotions in balance.
10. When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people.
11. I'm intolerant and impatient towards those aspects of my personality I don't like.
12. When I'm going through a very hard time, I give myself the caring and tenderness I need.
13. When I'm feeling down, I tend to feel like most other people are probably happier than I am.
14. When something painful happens I try to take a balanced view of the situation.
15. I try to see my failings as part of the human condition.
16. When I see aspects of myself that I don't like, I get down on myself.
17. When I fail at something important to me I try to keep things in perspective.
18. When I'm really struggling, I tend to feel like other people must be having an easier time of it.
19. I'm kind to myself when I'm experiencing suffering.
20. When something upsets me I get carried away with my feelings.
21. I can be a bit cold-hearted towards myself when I'm experiencing suffering.
22. When I'm feeling down I try to approach my feelings with curiosity and openness.
23. I'm tolerant of my own flaws and inadequacies.
24. When something painful happens I tend to blow the incident out of proportion.
25. When I fail at something that's important to me, I tend to feel alone in my failure.
26. I try to be understanding and patient towards those aspects of my personality I don't like.

Date:

Participant number:

WHO-5 Well Being Index

Please indicate (with a tick) for each of the five statements which is closest to how you have been feeling over the last week

Over the last week...

	All the time	Most of the time	More than half the time	Less than half the time	Some of the time	At no time
1. I have felt cheerful and in good spirits						
2. I have felt calm and relaxed						
3. I have felt active and vigorous						
4. I woke up feeling fully rested						
5. My daily life has been filled with things that interest me						

Thank-you

DATE:

Participant Number:

HELPFUL ASPECTS OF THERAPY FORM (H.A.T.) (10/93)

1. Of the events which occurred in this session, which one do you feel was the most **helpful** or **important** for you personally? (By "event" we mean something that happened in the session. It might be something you said or did, or something your therapist said or did.)

2. Please describe what made this event helpful/important and what you got out of it.

3. How helpful was this particular event? Rate it on the following scale.
(Put an "X" at the appropriate point; half-point ratings are OK; e.g., 7.5.)

HINDERING <-----				Neutral	-----> HELPFUL			
1	2	3	4	5	6	7	8	9
-----	-----	-----	-----	-----	-----	-----	-----	
E	G	M	S		S	M	G	E
X	R	O	L		L	O	R	X
T	E	D	I		I	D	E	T
R	A	E	G		G	E	A	R
E	T	R	H		H	R	T	E
M	L	A	T		T	A	L	M
E	Y	T	L		L	T	Y	E
L		E	Y		Y	E		L
Y		L				L		Y
		Y				Y		

4. About where in the session did this event occur?

5. About how long did the event last?

6. Did anything else particularly **helpful** happen during this session?

YES NO

(a. If yes, please rate how helpful this event was:

_____ 6. Slightly helpful

_____ 7. Moderately helpful

_____ 8. Greatly helpful

_____ 9. Extremely helpful

(b. Please describe the event briefly:

7. Did anything happen during the session which might have been **hindering**?

YES NO

(a. If yes, please rate how hindering the event was:

_____ 1. Extremely hindering

_____ 2. Greatly hindering

_____ 3. Moderately hindering

_____ 4. Slightly hindering

(b. Please describe this event briefly:

APPENDIX 5
SEMI-STRUCTURED INTERVIEW QUESTIONS

Interview Schedule

Sitting meditation – 10 minutes.

General experiences of the experience and effects of the group.

This section should explore participant's own views about what benefits and costs accrued from taking part in the programme. The aim here is to let the participants' experience speak for itself to see what they spontaneously report before we move on to ask questions based on our own hypotheses. The benefits may or may not be diabetes specific and could include things that are not specific to mindfulness but are part of any group experience.

- What do people think they have gained from taking part?
- What is it that was helpful about taking part?
- How has the group/programme been helpful to you?
- What specific things have you found it helpful for?
- Can you describe how you have found it helpful?
- Was there anything that happened as a result of taking part in the group that you did not expect?
- Did people experience anything negative as a result of taking part of this group?
- Has taking part in this group been unhelpful in any way?
- Tell me more about that/these things...

Participants' perceptions of the mechanisms of change.

The aim of this section is to gain a sense of the participants understanding of how the group was helpful. In the initial stages of this section general questions should be asked about participants views, although in later stages we are interested in finding out about whether the following features figured in their experience:

Potential useful questions...

- If you had to explain to someone else who knew nothing about mindfulness how it helped you to make these changes, what would you say?
- Mindfulness is about relating to difficulty in a different way. Can you tell me about how it has changed the way you approach any areas of difficulty? What have been the implications of changing the way in which you approach things?

Impact on their views of Diabetes and their Diabetes Self-Management

We are particularly interested in whether participants connected the experience of mindfulness with their experience of diabetes and what they think about this connection in relation to changing their behaviour.

- We have talked about how mindfulness can help us to relate differently to difficult situations. Diabetes can also present people with difficulties. Do any of you think that taking part in the group has changed your relationship with Diabetes? Could you give specific examples of how you know this has happened? Has taking part in the group changed anything about how you manage your Diabetes? Could you give specific examples of this?
- How would you describe your relationship with diabetes prior to the course... has the course produced any changes in this? Could you describe the changes...
- Do you think that the benefits of the programme were specific to Diabetes or did it apply to other areas of your life?
- Would it have changed your experience of the group if there had been other people with chronic conditions, not just people with Diabetes?

Views on the structure and usefulness of the programme

- Would you recommend that this programme be made available to other people with Diabetes? How do you think it would benefit them?
- Is there anything about the programme that you would change to make it more useful? Is there anything that you think that the programme should include to make it more useful?
- In the original mindfulness programme participants were asked to commit to 45 minutes of practice every day. Cast your mind back to when you were first thinking about coming on the programme:

- Do you think that you would have still come on the programme if we had made this request?
- If no, could you explain why this would have put you off?

ENDING

- Is there anything that you would like to say about taking part in this group – or even this focus group – that we have not yet covered?
- Can I invite you each to say one word that captures your experience of being on the programme?

SITTING MEDITATION

APPENDIX 6
TRANSCRIPTION KEY

Transcription Key

Identity of speaker identified by participant number e.g. G1 or I for interviewer

T = turn (turn in conversation) which have been numbered in order to allow the quotes in the paper to be located in the transcripts.

FG = focus group

VC = validity check

L = line number in original transcription

(not) = the transcriber is uncertain what was said but can make a reasonable guess

[diabetes] = enclose comments added by the transcriber, to make it clear what was referred to, or to indicate an interjection from another speaker or an interactional feature such as [laughs].

Ellipsis ... = speaker trails off

APPENDIX 7

EXAMPLE PROCESS OF QUALITATIVE ANALYSIS

Example of Qualitative Analysis

<p>FG, T113, I:</p>	<p>Well the kindness and also the awareness of your body, and I wondered sort of what you feel, what differences that may have made to managing the diabetes, for you do you think?</p>	<p>Asking how the changes G10 attributes to mindfulness relate to her experience of managing her diabetes</p>
<p>FG, T114, G10:</p>	<p>Well, I think it's about not being so strict, not being so punishing to yourself if things go wrong.</p> <p>I mean, I don't want to go all through you know my history again but I think there's a danger that we... that if we don't have complete success, we go completely the other way and are very, get very despondent, depressed, and you know deal with it or like ignore it and you know have a great old time and drink ourselves... you know to have a party.</p> <p>But um, I suppose it's, just thinking that possibly, you know that thing about it's OK, it's OK because sometimes it won't go right, sometimes you will get you know high levels of blood sugar an awful day or an awful year and you'll just be sick to death of it. But you can... you know, not to give up because you can't achieve perfection, you just try. And come back to it again, start again...</p>	<p>How self-compassion cuts her perfectionism</p> <p>Describing her previous pattern when the perfectionistic strategy to self-management failed (using avoidant coping and distraction to cope with feeling low)</p> <p>"Letting be"/acceptance cuts the perfectionistic cycle in her diabetes self-management</p> <p>Realising perfectionism doesn't work</p>
<p>FG, T115 I:</p>	<p>So it sounds like a very different way of being with difficulty and being with the diabetes. And I wondered if you feel that by, you know, that different relationship with it, you feel that you notice... It certainly sounds like a lot of acceptance but I wondered also, doing anything to... Have you noticed any... are you doing anything differently?</p>	<p>Summarising and asking for specific examples of behaviour change.</p>

<p>FG, T116, G10:</p>	<p>Well I do, I do, I mean... I'm sort of struggling here because I deeply resent it, you know, and deeply sort of...</p> <p>you know I also, you know [G8], don't like people telling me what to do, you know and it's like diabetes is telling me what to do,</p> <p>so I raged for a long, long time.</p> <p>So I wouldn't say I was totally sort of accepting and Christian (unclear)</p> <p>But I think it is about just actually being tired of struggling so much because you can't change it.</p> <p>And so I think what I've been doing is I think, well, oh well I'll just take the bloody blood sugar level and find out. And I have been doing that much more often. And while sometimes you do get high blood sugar levels, now I know that it's high then I can bring it down again, rather than thinking, well I wonder what it is. I suspect... I suppose it's like facing up to bad news in a way.</p>	<p>Diabetes emotions: resentment</p> <p>Issues about control and being controlled (feeling diabetes as an external imposition)</p> <p>Diabetes emotions: anger</p> <p>Previous non-acceptance of diabetes</p> <p>Coming to accept the situation</p> <p>How mindfulness/self-compassion has helped: testing her blood more often</p> <p>Facing up to diabetes rather than using previous avoidant coping strategy</p>
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